1	DANIEL C. CEDERBORG County Counsel – SBN 124260	E-FILED 6/15/2023 3:49 PM
2	KYLE R. ROBERSON	Superior Court of California County of Fresno
3	Deputy County Counsel – SBN 285735 FRESNO COUNTY COUNSEL	By: C. York, Deputy
4	2220 Tulare Street, 5th Floor Fresno, California 93721	
5	kroberson@fresnocoutyca.gov	
6	Telephone: (559) 600-3479 Facsimile: (559) 600-3480	Exempt From Filing Fees Pursuant To Government Code Section 6103
7	Attorneys for FRESNO COUNTY DEPARTMENT OF PUBLIC HEALTH	
8		
9	SUPERIOR COURT OF CALIFORNIA, COUNTY OF FRESNO	
10	CIVIL UNLIMITED DIVISION	
11		
12	IN RE PROPERTY LOCATE AT	Case No. 23CECG00912
13	850 "I" STREET, REEDLEY, CALIFORNIA 93654	FRESNO COUNTY DEPARTMENT OF
14	[APN 368-010-64S]	PUBLIC HEALTH'S APPLICATION FOR ABATEMENT WARRANT;
15	Property Owner: AY-NC-LP Responsible Parties: Prestige Biotech, Inc, a	DECLARATIONS OF HUMERO PRADO IN SUPPORT
16	Nevada Corporation; and Universal	(Code Civ. Proc. § 1822.50 et seq)
17	Meditech, Inc, a California Corporation	[Proposed Abatement Warrant filed
18		concurrently]
19		
20	COUNTY OF FRESNO DEPARTMENT OF PUBLIC HEALTH ("Fresno County	
21	Public Health"), acting as the health department for the City of Reedley, hereby applies to this	
22	Court for a warrant, pursuant to Code of Civil Procedure section 1822.50 et seq., authorizing	
23	Fresno County Public Health to enter upon the premises commonly known as 850 "I" Street, in	
24	the City of Reedley, County of Fresno, in the State of California, further identified as Assessor's	
25	Parcel Number 368-010-64S (hereinafter the "Property"). Fresno County Public Health has	
26	attempted but has been unable to obtain the cooperation from the property owner AY-NC-LP	
27	("Owner"), and Prestige Biotech, Inc. ("Prestige Biotech"), the commercial tenant in possession,	
28	to comply with valid health officer orders issued by Dr. Rais Vohra, Interim Health Officer of	

the County of Fresno ("Health Officer") on May 31, 2023, and June 9, 2023, to abate biological materials and infectious agents that, given the unsafe and unsanitary conditions of the Property may, if left unabated, be a source of the spread of communicable diseases and therefore, constitute a public nuisance. By this warrant, Fresno County Public Health seeks to abate potential sources of communicable diseases and public nuisance conditions as follows: all biological material, blood, blood product, serums, other bodily fluids, cultures, viral, bacterial and parasitic agents, human and animal tissue; vials, containers, equipment, fabric, and other materials contaminated with blood, serum, bodily fluids, or infectious agents.

Fresno County Public Health contends that it is now necessary to abate the source of communicable diseases, infectious agents, and other biological material stored on the Property that are a threat to public health and safety and constitute a public nuisance. This Application is based upon the Memorandum of Points and Authorities, the declaration of Humero Prado, included herein with this Application; the Court's file in Fresno County Superior Court case number 23CECG00912; and upon other documentary evidence and oral testimony, which may be presented to the Court.

MEMORANDUM OF POINTS AND AUTHORITIES

I.

INTRODUCTION

Fresno County Public Health respectfully requests this Court (1) issue an Abatement Warrant for entry into the warehouse located at 850 "I" Street, Reedley, California 93654, located in the incorporated area of the City of Reedley, further identified as Assessor's Parcel Number 368-010-64S (hereinafter the "Property") (Declaration of Humero Prado ("Prado Decl."), ¶ 4), and (2) that the warrant provide for abatement in the Owner's, Prestige Biotech's and UMI"s absence and for the use of reasonable force to open any locked door or storage device within the warehouse to effectuate the warrant.

The known and noticed violations of state law include the following: (1) the operation of an unlicensed and unregulated laboratory; (2) the storage of biological material, medical waste, and infectious agents in an unsafe and unsanitary manner and within a building unfit for storge of

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such biological materials; (3) the unsafe maintenance of infectious agents that potentially cause human mortality; and (4) the disposal of medical waste in violation of the California Medical Waste Management Act.

The Owner and Prestige Biotech have had ample opportunities and a reasonable time to correct the violations and abate the unsafe, unsanitary, hazardous and nuisance conditions present. (Prado Decl., ¶¶ 38-55.) Therefore, Fresno County Public Health seeks an order from this Court to permit Fresno County Public Health, its employees, and any contractors hired by the County to enter onto the Property for the purpose to abate the biological material, medical waste and infectious agents stored in the warehouse on the Property.

II.

STATEMENT OF FACTS

The Property is located within the incorporated area of the City of Reedley ("City") and is subject to an open code violation by the City. (Prado Decl., ¶ 4) Fresno County Public Health operates as the health department within the incorporated area of the City of Reedley, and Dr. Rais Vohra acts as the health officer for the City. (Id., at ¶ 5.) Since October 2022, Universal Meditech, Inc. ("UMI"), and Prestige Biotech has been operating an unlicensed and unregulated laboratory within a large warehouse located on the Property. (Id., at \P 7.) Prestige Biotech is the successor to UMI, a California corporation, which is now defunct and going through the bankruptcy process. (Id., at ¶ 8.) UMI transferred biological material and laboratory equipment from a previous site located in the City of Fresno. (*Ibid.*) The warehouse is patently unfit for this purpose. During its code enforcement investigation, the City noted substandard building conditions including, unpermitted and faulty electrical installations, building code violations, inadequate water supply, inadequate ventilation, fire hazards, storage of hazardous and combustible materials, and pest infestation. (Id., at \P 10.) However, the City had grave concerns over what appeared to be the laboratory operation on site, storage and use of biological material, and experimentation on laboratory mice. The City contacted Fresno County Public Health to assist in the City's enforcement efforts because unknown biological material and toxic chemicals were discovered on the Property. (Ibid.) The City also contacted the California Department of

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Toxic Substance Control ("DTSC"), the California Department of Public Health ("CDPH"), and the Federal Bureau of Investigations ("FBI"). (*Id.*, at ¶ 6.)

On March 3, 2023, City staff conducted an inspection of the warehouse and observed electrical, fire, building, municipal and Health and Safety Code violations. Due to the extent of these violations, the City posted the warehouse on the Property "Unsafe to Occupy." (Prado Decl., ¶¶ 10-11.) With the City posting the warehouse as "Unsafe to Occupy," all employees of the business entities operating the unlicensed laboratory have vacated the building. Employees, agents, and principals of the operators of the unlicensed laboratory are not permitted to enter the building without authorization from City officials. As a result, the City maintains control and access to the building. (Id., at ¶ 11.)

On March 16, 2023, the City returned to the Property and inspected the warehouse pursuant to the City's first inspection warrant. Fresno County Public Health staff and CDPH staff accompanied the City during this inspection. The City documented several building and safety code violations, including but not limited to electrical issues. (Prado Decl., ¶ 14.))CDPH documented embargoed medical devices, e.g. COVID tests and pregnancy tests, believed to be developed on site. Certain rooms of the warehouse were found to contain several vessels of liquid and various apparatus. In open view during this inspection, Fresno County Public Health staff also observed blood, tissue and other bodily fluid samples; serums; and thousands of vials of unlabeled fluids and suspected biological material. (Ibid.) Various laboratory equipment was also found to include a biological safety cabinet and centrifuge. Cold temperature storage units were also observed, which included 2 ultralow temperature freezer units (-80 and -60 degrees C) and 29 refrigerators/freezers (-20 degrees C). (Ibid.) Ultralow temperature freezers raised concerns that infectious agents were stored on site. During this inspection a room was found housing hundreds of laboratory mice. (*Ibid.*) A person associated with Prestige Biotech and who appeared to be in control of the Property, informed the investigators that these mice were genetically engineered to catch and carry the COVID-19 virus. (Id., at ¶ 15.) The mice held in the warehouse appeared to be in distress and were kept in inadequate conditions in overcrowded cages and there was a lack of food and water for the animals. (Id., at ¶ 19.)

On April 12, 2023, the City returned to inspect the warehouse under an abatement warrant to remove and, if necessary, euthanize the laboratory mice held in inhumane conditions. With the assistance of a veterinarian, the City euthanized 773 mice with 178 mice found to be already deceased at the time of execution of the abatement warrant. (Prado Decl., ¶ 21.)

On April 21, 2023, Fresno County Public Health staff conducted an inspection of the Property pursuant to the Order of the Health Officer of the County of Fresno for the Inspection of Facility Located at 850 "I" Street, Reedley, California 93654 ("Inspection HOO"). (Prado Decl., ¶¶ 24-25.) During this inspection, Fresno County Public Health staff observed biologicals stored and kept in hazardous and non-compliant conditions, the presence of multiple infectious agents (confirmed by CDC) and pursuant to Title 17 California Code of Regulations Section 2500. Fresno County Public Health staff also observed the 32 refrigerators and freezers. A number of these refrigerators and freezers had either stopped functioning or were failing due to an inadequate power supply. (*Id.*, at ¶ 25.)

On May 1, 2023, CDPH conducted a medical waste management investigatory inspection at the Property. (Prado Decl., ¶ 27.) CDPH staff observed 32 refrigerators and freezers. CDPH staff also observed several pieces of laboratory equipment, such as incubators and centrifuges. 30 of the 32 refrigerators and freezers were visually inspected. The two uninspected storage units were the minus 80C freezer and a refrigerators/freezer that CDPH staff was advised not to open due to biologicals stored within. In several freezers CDPH staff observed containers labeled as serum or plasma (of unknown origin) and/or with the name of an infectious agent. (*Ibid.*) A substantial number of the containers were unlabeled and CDPH staff was unable to discern the contents of these containers. Many of the indecipherable containers appeared to contain blood, or a blood product, such as serum, or other bodily fluids. In several of the refrigerators and freezers, CDPH staff observed numerous vials of pharmaceuticals. (*Ibid.*) CDPH staff also observed what appeared to be a biohazardous waste container shrink wrapped to a pallet. (*Id.*, at ¶ 28.) The container was inaccessible due to safety concerns and CDPH staff was unable to inspect the container or its contents. This container appeared to have been moved from another location to this facility. CDPH staff also observed a wire metal storage rack with a box that contained one

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unused red biohazard autoclave bag and a box of unused orange biohazard autoclave bags. The red biohazard bag was not marked and certified.(*Ibid*.)

At all times during the UMI's and/or Prestige Biotech's operation of the laboratory at the Property, it has failed to comply with the requirements of proper medical waste transport and disposal pursuant to the Medical Waste Management Act ("MWMA"). (Prado Decl. ¶¶ 16, 22-23, 27.) Prestige Biotech was disposing of deceased laboratory mice, considered to be medical waste, without the use of a licensed medical waste hauler. (*Id.*, at ¶ 16.)

From May 2 through May 4, 2023, staff from CDC's Division of Select Agents and Toxins inspected the Property. (Prado Decl., ¶ 31.) CDC staff determined that at least 20 potentially infectious agents of risk group 2 and risk group 3 were present as follows:

Potentially Infectious bacterial agents present:

- o Chlamydia trachomatis
- o E. coli (recombinant strains)
- Mycobacterium tuberculosis
- Mycoplasma pneumoniae and general Mycoplasma species
- o Neisseria meningitidis
- Nostoc species
- o Sphingobacterium heparinum
- o Streptococcus pneumoniae and Streptococcus species
- o Toxoplasma gondii

Potentially Infectious viral agents present:

- Hepatitis B virus
- Hepatitis C virus
- Dengue virus
- Human Immunodeficiency Virus 1 and 2
- o Human Herpes virus 1 (Herpes simplex virus)
- o Human Herpes virus 5 (Human Cytomegalovirus)
- Respiratory Syncytial virus

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- o Rubella virus
- o Serve Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

Potentially Infectious parasites present:

o Malaria (believed to be *P. falciparum* from Nigeria from the year 2000. (*Id.*, at \P 33.)

CDC staff communicated their concerns to Fresno County Public Health staff that the infectious agents listed above were stored in the warehouse on the Property (*Id.* at ¶¶ 35-36.)

The Health Officer and Fresno County Public Health staff are gravely concerned about the storage of potentially infectious bacterial, viral, and parasitic agents present at the Property and the health and safety risk to the public by these infectious agents. (Prado Decl., ¶ 37.)

In response to the inspections by the City, CDPH, CDC and Fresno County Public Health staff's own observations, the Health Officer issued Health Officer Order for County of Fresno to Close Business Operations and Abatement Biologicals Located at 850 "I" Street, Reedley, CA 93654 ("Second HOO"). (Prado Decl., ¶ 38.) The Second HOO demanded that Prestige Biotech abate all biological materials stored in the warehouse on the Property. The Second HOO was issued as result of the City's attempts at gathering contact information for Prestige Biotech's authorized representatives, repeated requests for complete lists of all biologicals present, and an inspection pursuant to the Inspection HOO dated April 21, which revealed biologicals in hazardous and non-compliant conditions, the presence of multiple infectious agents, and multiple City building and fire code violations, including failing refrigeration, and documented out of compliance electrical additions, pest infestation at the premises, and evidence of increasing non-compliance, and to protect the public from the spread or exposure to the identified infectious agents found on the Property. (Ibid.) The Second HOO demanded the Operators undertake the following actions: (1) identify an authorized agent on behalf of Prestige Biotech who is authorized to conduct business in California; and (2) produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State and local regulations and properly dispose of all medical waste in compliance with the MWMA. (*Id.*, at ¶ 39.)

David He, who held himself out to be associated with Prestige Biotech, attempted to communicate with Fresno County Public Health in response the Second HOO. (Prado Decl., 41.) However, Mr. He failed to provide an adequate response to the Second HOO and did not provide a satisfactory biological abatement and disposal plan. Most concerning was that Mr. He disputed that infectious agents were stored on the Property despite the clear documentation by the CDC. (*Id.*, at ¶¶ 42-45.)

Based on this attempted but insufficient response to the Second HOO, Fresno County Public Health extended the time for Prestige Biotech and UMI to provide a satisfactory response and plan to satisfy the Second HOO. (Prado Decl., ¶¶ 46-47.)

On June 9, 2023, the Health Officer issued Amended Health Officer Order for County of Fresno to Close Business Operations and Abatement Biologicals Located at 850 "I" Street, Reedley, CA 93654 ("Amended HOO"). (Prado Decl, ¶ 48.) The Amended HOO demanded the Operators undertake the following actions by June 11, 2023: (1) identify an authorized agent on behalf of Prestige Biotech who is authorized to conduct business in California; and (2) produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State and local regulations, and properly dispose of all medical waste in compliance with the MWMA. (*Id.*, at ¶ 49.)

Prestige Biotech failed to provide a timely satisfactory response to the Second HOO and Amended HOO. Despite attempted communication by David He, Mr. He failed to provide legally sufficient documentation and Prestige Biotech and UMI have failed to produce legally sufficient documentation that Mr. He is an authorized agent or sufficiently identify any authorized to act on behalf and bind Prestige Biotech and/or UMI. Prestige Biotech and UMI has further failed to produce a biological abatement plan for the disposal and transport of the biological material, medical waste and infectious agents. Again, David He disputed that infectious agents were kept on the Property.

III.

ABSENT CONSENT, A WARRANT IS REQUIRED PRIOR TO ENTRY FOR PURPOSES OF INSPECTION AND ABATEMENT

A. Warrant Requirement

The Fourth Amendment generally requires that the government obtain an inspection warrant for a non-consensual entry onto private property to conduct an inspection and abate a public nuisance. (Camara v. Municipal Court of City and County of San Francisco (1967) 387 U.S. 523, 528-529; Gleaves v. Waters (1985) 175 Cal.App.3d 413, 418; see also Conner v. City of Santa Ana (9th Cir. 1990) 897 F.2d 1487, 1490.) Government officials engaged in the abatement of a public nuisance, in the absence of consent or exigent circumstance, must have a warrant to enter any private property where such entry would invade a constitutionally protected privacy interest. (Gleaves, at pp. 419-420; see also Flahive v. City of Dana Point (1999) 72 Cal.App.4th 241, 246.) However, the warrant requirement does not extend to all entries onto private property for nuisance abatement, only those which infringe upon constitutionally recognized expectations of privacy. (Gleaves, at pp. 419-420; City and County of San Francisco v. City Investment Corp. (1971) 15 Cal.App.3d 1031, 1039.)

B. Statutory Authority for Issuance of an Inspection Warrant

This Court is authorized to issue a warrant for inspection and abatement. Section 1822.50 of the Code of Civil Procedure¹ provides that:

An inspection warrant is an order, in writing, in the name of the people, signed by a judge of a court of record, directed to a state or local official, commanding him to conduct any inspection required or authorized by state or local law or regulation relating to building, fire, safety, plumbing, electrical, health, labor, or zoning

The inspection warrant shall issue under Section 1822.54,

If the judge is satisfied that the proper standard for issuance of the warrant has been met, he or she shall issue the warrant particularly describing each place, dwelling, structure, premises, or vehicle to be inspected and designating on the warrant the purpose and limitations of the inspection, including the limitations required by this title.

In City and County of San Francisco v. Municipal Court (1985) 167 Cal.App.3d 712, 719, the court stated that a civil inspection warrant must be justified by reasonable government

¹ All future statutory references are to the Code of Civil Procedure unless otherwise stated.

interests. Where the governmental interest at stake is to enforce building standards and thereby prevent conditions that are hazardous to public health and safety, the test for determining reasonableness may vary with the municipal program being enforced. (*Id.*) Thus, the court authorized an inspection warrant to allow redevelopment officers to enter private property to determine whether that property complied with redevelopment standards. (*Ibid.*)

While there is no statutory procedure for issuance of a warrant authorizing entry into private property specifically to abate a public nuisance, case law clearly establishes the validity of the issuance of an abatement warrant. In *Conner v. City of Santa Ana*, the court held, "California courts have rejected, for purposes of the warrant requirement, any distinction between inspection and abatement of a declared public nuisance." (*Conner v. City of Santa Ana, supra*, 897 F.2d at p. 1491.) The courts in *Gleaves* and *Flahive* held that an abatement warrant procedure that follows the statutory requirements of an inspection warrant is sufficient to pass constitutional muster. (*Gleaves v. Waters, supra* 175 Cal.App.3d at p. 420; *Flahive v. City of Dana Point, supra*, 72 Cal.App.4th at p. 246.) Therefore, California has but one procedure for the issuance of a warrant to inspect and abate state or local law or regulation relating to building, fire, safety, plumbing, electrical, health, labor, or zoning, California Code of Civil Procedure section 1822.50 *et seq.* (Code Civ. Proc., § 1822.50 [emphasis added].)

C. Abatement is Authorized Under the County's Authority Under State Law

The Health Officer issued health officer orders under the authority granted to the Health Officer under California Health and Safety Code sections 120175 and 120275; Title 17 California Code of Regulations section 2501; and Article XI of the California Constitution. To prevent the spread of infectious or communicable disease, the Health and Safety Code section 120175 provides that "[e]ach health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the department, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases." Similarly, Title 17 Code of Regulations section 2501 authorizes

a local health officer to "take appropriate steps to prevent or control the spread of the disease."

By this warrant, Fresno County Public Health seeks to abate by destruction biological material, infectious agents, and medical waste in compliance with the Medical Waste Management Act ("MWMA"), California Health and Safety Code section 117600, *et seq.* An "infectious agent" is defined as "a type of microorganism, bacteria, mold, parasite, or virus, including, but not limited to, organisms managed as Biosafety Level II, III, or IV by the federal Centers for Disease Control and Prevention, that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings." (Health & Safety Code § 117675.) "Medical waste" is defined as

any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resources Conversation and chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such cremation or interment; waste generated in research pertaining to the production or testing of microbiological; waste generated in research using human or animal pathogens; sharps and laboratory waste that possess a potential risk of infection to humans; generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes. (Health & Safety Code § 117690, subd. (a).)

In addition to those materials that meet the definition of "medical waste" under the MWMA, items that meet the definition of "Regulated Waste" under the California Bloodborne Pathogen rule (Cal. Code Reg. tit. 8, § 5193) must be handled, stored, treated, and disposed of as medical waste. "'Regulated Waste' means waste that is any of the following: (1) Liquid or semiliquid blood or OPIM; (2) Contaminated items that: (A) Contain liquid or semi-liquid blood, or are caked with dried blood or OPIM; and (B) Are capable of releasing these materials when handled or compressed; (3) Contaminated sharps; (4) Pathological and microbiological waste containing blood or OPIM; and (5) Regulated Waste include "medical waste" regulated by Health and Safety Code Sections 117600 and 118360." (Cal. Code Reg., tit. 8, § 5193.) The MMA requires that "[a]ll medical waste be hauled by a registered hazardous waste hauler." (Health & Safety Code § 118025.)

Violations of the HOO are a public nuisance subject to abatement by warrant. A public

nuisance is "anything which is <u>injurious to health</u>... or is indecent or offensive to the senses, or an obstruction of the free use of property, so as to interfere with the comfortable enjoyment of life or property," which affects a community or considerable number of persons. (Civ. Code, §§ 3479-3480.) Civil Code section 3491 authorizes abatement as a proper remedy for a public nuisance. Abatement proceedings for a public nuisance are thus authorized by state law and are within the police powers of the state. (*Scott v. City of Del Mar* (1997) 58 Cal.App.4th 1296, 1305; *City of Costa Mesa v. Soffer* (1992) 11 Cal.App.4th 378, 383.) Based on general law regarding the abatement of a public nuisance, pursuant to Civil Code 3491, and the broad authority of a local health officer to take any means necessary to prevent the spread of communicable disease, pursuant to Health and Safety Code section 120175, the abatement of the biological materials present on the Property are authorized by state law.

D. All Prerequisites for the Issuance of An Inspection and Abatement Warrant Are Met in the Instant Application

The procedural requirements for issuance of an inspection warrant are provided for in Section 1822.51 as follows:

An inspection warrant shall be issued upon cause unless some other provision of state or federal law makes another standard applicable. An inspection warrant shall be supported by an affidavit, particularly describing the place, dwelling, structure, premises, or vehicle to be inspected and the purpose which the inspection is to be made.

This Application satisfies all prerequisites for the issuance of an inspection and abatement warrant. As required by Section 1822.54, the declaration of Humero Prado, in support of the warrant, describes each building, place, structure, or premises to be inspected. The warrant describes the purpose and limitations of the warrant to authorize the abatement of (1) all biological material, including but not limited to, blood, tissue and other bodily fluid sample, and serums; (2) all biological material deemed to be medical waste; (3) all infectious agents; (4) all containers, vials, boxes, bags, laboratory equipment and other storage devices that store or have been contaminated by biological material, medical waste and/or infections agents, and any other personal property contaminated by biological material, medical waste and/or infections agents.

Continued efforts to seek consent would be futile because Prestige Biotech and UMI have refused to provide a satisfactory response to the health officer orders and failed to provide a legally sufficient disposal and transportation plan for the biological material stored on site despite ample time to do so. Furthermore, the proposed Abatement Warrant is effective for not more than fourteen (14) days as required by Section 1822.55. Lastly, an entry pursuant to the proposed Abatement Warrant will not be made during the time prohibited by Section 1822.56 between 6:00 p.m., of any day and 8:00 a.m. of the succeeding day. However, reasonable circumstances exist that this inspection and abatement be made in the absence of an owner or responsible party and the warrant authorize the use of reasonable force to enter the Property and any locked rooms or storage device where biological material, medical waste and/or infectious agents may be kept. The proposed Abatement Warrant is filed concurrently with this Application.

1. Probable Cause Exists for Issuance of an Abatement Warrant

Section 1822.52 provides that:

Cause shall be deemed to exist if either reasonable legislative or administrative standards for conducting a routine or area inspection are satisfied with respect to the place, dwelling, structure, premises, or vehicle, or there is reason to believe that a condition of nonconformity exists with respect to the place, dwelling, structure, premises, or vehicle.

Ample documentation exists to show that Prestige Biotech continues to keep biological material, medical waste, and infectious agents within the warehouse on the Property. These materials are a serious threat to public health and safety. The infectious agents found in the warehouse are, by definition, cause or significantly contribute to the cause of increased morbidity or mortality of human beings. (Prado Decl., ¶ 33, 57; see also Health & Safety Code § 117675.) The Health Officer is empowered under the laws of this State to take measures as may be necessary to prevent the spread of infectious and communicable diseases. (Health and Safety Code § 120175.) Prestige Biotech and UMI have had ample time to bring its operations in to compliance with the law. Prestige Biotech's and UMI's history and pattern and practice of maintaining the premises in an unsafe and unsanitary manner and failure to follow federal and

state regulations on the handling of biological material, medical waste and infectious agents raises grave concerns as to public health and safety. (Prado Decl., \P 58.) The Health Officer by issuing the health officer orders now seeks to abate the biological material, medical waste and infectious agents kept within the warehouse on the Property as necessary action to prevent the spread of infectious and communicable diseases. (Id., at \P 59.)

2. Reasonable Circumstances for Failure to Seek Consent to Inspect

According to Section 1822.56, the affidavit or declaration in support of an inspection warrant must establish that "consent to inspect has been sought and refused or circumstances reasonably justifying the failure to seek such consent."

Prestige Biotech and UMI have failed to produce a satisfactory biological abatement and disposal plan to properly dispose and, if permissible, transport certain biological material kept at the Property. Despite Fresno County Public Health initially attempting to communicate with Prestige Biotech to take reasonable prudent steps to safeguard public health and safety in Prestige Biotech's and UMI's handling of the biological material, medical waste, and infectious agents it maintains, Prestige Biotech has consistently refused to take such reasonably prudent steps and conduct its operations in compliance with Federal and State regulations. (Prado Decl., ¶¶ 59-60.) In fact, individuals purported to be associated with Prestige Biotech have disputed that infectious agents are kept at the Property. (Id..., at ¶¶ 44-45, 52.) Fresno County Public Health is also concerned that Prestige Biotech will attempt to secret away and transport the biological materials, medical waste and infectious agents from the Property, in violation of applicable Federal and State regulations, to a new laboratory facility within the City of Fresno. Abatement by Fresno County Public Health is necessary to prevent a public health crisis based on the history of Prestige Biotech's reckless handling of the biological material kept on site. (Id., at ¶¶ 59-60.)

3. Inspection Must be Made in the Absence of the Owner and Should Allow Reasonable Force if Necessary

Pursuant to Section 1822.56, "[a]n inspection pursuant to this warrant may not be made.

... in the absence of an owner or occupant of the particular place, dwelling, structure, premises, or vehicle unless specifically authorized by the judge upon a showing that such authority is

reasonably necessary." Furthermore, this Section provides that the court "may expressly authorize forcible entry where facts are shown sufficient to create a reasonable suspicion of a violation of state or local law . . . which, if such a violation existed, would be an immediate threat to health and safety." (*Ibid*.)

The purpose of the health officer orders and the Health Officer's authority to take measures to prevent the spread of infectious and communicable diseases is for the protection of life, health, welfare, safety of the general public and surrounding community. (Health and Safety Code \S 120175.) The warehouse on the Property is vacant and unoccupied with the City posting it "Unsafe to Occupy". (Prado Decl., \P 11.) However, Fresno County Public Health does not want its efforts to fully abate the biological material, medical waste and infectious agents to be thwarted by any locked doors or locked storge device. Therefore, good cause exists to authorize the use of reasonable force to open any such locked doors or storage devices. It is further impractical to allow the inspection and abatement to occur only if the Owner or Prestige Biotech's agents are physically present. In addition, the effectuation of the warrant will require coordination of multiple agencies and the County's contractors at public cost, and it is irresponsible to risk wasting those resources if the Owner, Prestige Biotech's representative, or UMI's representative is not present. Therefore, circumstances exist to justify execution of the warrant in the absence of an owner or occupant. (Id., at \P 61)

Similarly, the use of reasonable force to enter the property ensures that public resources will not be wasted, and the inspection and abatement required will not be frustrated by Owner, any occupants, or physical barriers of entry. Reasonable force will allow for a more organized and rapid inspection and abatement because it helps avoid or minimize unnecessary delay. (Prado Decl., ¶ 61.)

4. Appropriate Notice will be Provided to Owner

According to Section 1822.56, "notice that a warrant has been issued must be given at least 24 hours before the warrant is executed, unless the judge finds immediate execution is reasonably necessary in the circumstances shown."

Fresno County Public Health staff will attempt to contact an agent for the Owner and a

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representative for Prestige Biotech at least 24-hours before execution of the warrant before any abatement activity is scheduled to occur on the Property pursuant to the requested warrant.

IV.

CONCLUSION

Based upon the foregoing and the declaration of Humero Prado attached hereto, Fresno County Public Health respectfully requests that the Court issue an Abatement Warrant to permit Fresno County Public Health to enter onto the Property, with at least 24-hours' notice to the Owner and Prestige Biotech prior to entry, and enter the warehouse on the Property to complete the following abatement activity: (1) dispose of all biological material, including but not limited to, blood, tissue and other bodily fluid samples, and serums; (2) dispose of all biological material deemed to be medical waste; (3) dispose of all infectious agents; (4) dispose of all containers, vials, boxes, bags, laboratory equipment and other storage devices that store or have been contaminated by biological material, medical waste and/or infections agents, and any other personal property contaminated by biological material, medical waste and/or infections agents. Fresno County Public Health and the Health Officer is authorized to abate the biological material, medical waste, and infectious agents pursuant to state law to prevent the spread of infectious and communicable diseases. Fresno County Public Health requests the Court authorize entry by Fresno County health officials, County attorneys, deputy sheriffs, and Fresno County contractors hired to perform the abatement work, City of Reedley officials and staff, and representatives with CDPH, CDC, and FDA, and FBI.

Dated: June 15, 2023

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DANIEL C. CEDERBORG

County Counsel

/s/ Kyle Roberson By:

KYLE R. ROBERSON, Deputy

Attorneys for, COUNTY OF FRESNO DEPARTMENT OF PUBLIC HEALTH

SUPPORTING DECLARATION OF HUMERO PRADO

- I, Humero Prado, hereby declare:
- 1. I am over the age of 18 years and am a resident of the State of California.
- 2. I personally reviewed the file in this matter, and I am familiar with County of Fresno Department of Public Health ("Fresno County Public Health") records for the property located at 850 "I" Street, Reedley, California 93654, located in the incorporated area of the City of Reedley, further identified as Assessor's Parcel Number 368-010-64S (hereinafter the "Property"). All of the facts stated herein are within my personal knowledge, except for those matters stated on information and belief and, as to those matters, I believe them to be true. If called as a witness, I would testify as to the truth of the matters stated herein.
- 3. I am currently employed by the County of Fresno as the Assistant Director of the County of Fresno Department of Public Health ("Fresno County Public Health"). As part of my duties, I consult with David Luchini, Director of the County of Fresno Department of Public Health ("Director"); and Dr. Rais Vohra, Interim Health Officer of the County of Fresno ("Health Officer"), on matters involving public health and threats to public health. I also supervise Fresno County Public Health staff in their duties to investigate and address potential public health risks.

City of Reedley's Code Enforcement Action and Investigation

- 4. The City of Reedley ("City") is currently engaged in efforts to bring the Property into compliance with the City ordinance code, building code, and health code violations since March 3, 2023. I am informed and believe, based on information provided by the City, that the owner of record of the Property is AY-NC LP, a California Limited Partnership. I am informed and believe that the tenant in possession of the Property is a business identified as Prestige Biotech, Inc. ("Prestige Biotech"), a Nevada corporation unregistered to conduct business in California. The Property consists of a 1.73-acre parcel lot with an industrial warehouse.
- 5. Fresno County Public Health operates as the health department within the incorporated area of the City of Reedley, and Dr. Rais Vohra acts as the health officer for the City of Reedley.

- 6. The City contacted Fresno County Public Health to assist in the City's enforcement efforts because unknown biological material and toxic chemicals were discovered on the Property. The City also contacted the California Department of Toxic Substance Control ("DTSC"), the California Department of Public Health ("CDPH"), and the Federal Bureau of Investigations ("FBI").
- 7. Prestige Biotech and Universal Meditech, Inc. ("UMI") have operated an unlicensed and unregulated laboratory on the Property since October 2022.
- 8. I am informed and believe that Prestige Biotech is the successor to UMI, a California corporation, which is now defunct and is going through the bankruptcy process. I am further informed and believed the UMI transferred biological material and laboratory equipment to the warehouse on the Property from a previous site located in the City of Fresno.
- 9. Beginning in December 2022, Fresno County Public Health multiple unsuccessful attempts to communicate with the operators of the unlicensed laboratory to ascertain the contents and items at the facility.
- 10. On March 3, 2023, City staff inspected the Property to investigate potential building violations for the laboratory facility that was established within the warehouse on the Property. City staff observed multiple building and municipal code violations throughout the facility. There were multiple electrical circuits that were added to the facility without permits. An open and exposed electrical panel with new conduits and conductors were added without permits. An additional electrical panel was added without permits that had multiple circuits running into locked areas of the building. A new compressor unit was observed mounted upon a pallet feeding into a cold storage area that was locked. There was a garden hose attached to a service sink that fed into the locked portion of the building through a hole in the rear wall. A hole had been cut into the rear door to allow for ventilation from the operation of unknown equipment. City staff believed that the hole was used to ventilate a room to house laboratory mice due to the pungent odor of rodent excrement in the area. City staff also found various chemicals and materials stored and utilized by employees at the Property. City staff contacted Fresno County Public Health, along with other state and federal agencies, regarding the

potential public health and safety threat presented by these unknown substances.

- 11. As a result of this March 3, 2023 inspection and the observations of the electrical, fire, building, municipal and Health and Safety Code violations, the City posted the warehouse on the Property as "Unsafe to Occupy." With the City posting the warehouse as "Unsafe to Occupy," all employees of the business entities operating the laboratory have vacated the building. Employees, agents, and principals of the operators of the laboratory are not permitted to enter the building without authorization from City officials. The City maintains control and access to the building.
- 12. On March 10, 2023, in Fresno Superior Court case number 23CECG00912, the City requested an inspection warrant due to concerns of the building code, electrical code and other unsafe conditions observed at the Property.
- 13. On March 13, 2023, the Court issued a First Inspection Warrant to authorize the City and representatives from Fresno County Public Health, DTSC, CDPH, and FBI to enter the Property and interior of the industrial warehouse and inspect for Health and Safety Code, Building Code, Municipal Code violations, and other violations of state and federal law and regulations.
- 14. On March 16, 2023, the City executed this First Inspection Warrant and carried out an inspection of the entirety of the warehouse on the Property. The City documented several building and safety code violations, including but not limited to electrical issues. CDPH documented embargoed medical devices, e.g. COVID tests and pregnancy tests, believed to be developed on site. Certain rooms of the warehouse were found to contain several vessels of liquid and various apparatus. Fresno County Public Health staff also observed blood, tissue and other bodily fluid samples and serums; and thousands of vials of unlabeled fluids and suspected biological material. Various laboratory equipment was also found to include a biological safety cabinet and centrifuge. Cold temperature storage units were also observed, which included 2 ultralow temperature freezer units (-80 and -60 degree C) and 29 refrigerators/freezers (-20 degrees C). Ultralow temperature freezers raised concerns that infectious agents were stored on site.

- 15. During this March 16, 2023 inspection, a room was found housing hundreds of laboratory mice. Wang Zhaloin, a person who appeared to be in control of the warehouse on the Property, informed the investigators that these mice were genetically engineered to catch and carry the COVID-19 virus.
- 16. I am informed and believe UMI and Prestige Biotech have not employed the services of a licensed medical waste hauler during the course of the operation of the warehouse at the Property. I am informed and believe that since December 2022, UMI and Prestige Biotech were disposing of deceased laboratory mice, considered to be medical waste, without the use of a licensed medical waste hauler.
- 17. On March 17, 2023, City staff engaged in email communication with Xiuquin Yao, who purported to be the President of Prestige Biotech. City staff requested Ms. Yao provide any licenses or certifications permitting the experimentation on and breeding of these mice. Ms. Yao and Prestige Biotech failed to provide any certifications or licenses from any state or federal agency for storage and experimentation on mice and other laboratory activities at the Property. City staff observed the mice were being kept in inadequate conditions in overcrowded cages and there was a lack of food and water for the animals. No plan was provided by Ms. Yao regarding the care for the mice or location where the mice would be moved since the building was red tagged following the City's inspection on March 16, 2023.
- 18. On March 29, 2023, the City, after consulting with a veterinarian, filed an application for an Abatement Warrant to remove the mice from the Property.
- 19. On March 31, City code enforcement staff communicated with Xiuqin Yao, the purported President of Prestige Biotech. Ms. Yao informed City staff that biological materials and laboratory mice stored on the Property belong to UMI and were hastily moved to the Reedley site from a previous laboratory site believed to have been located in the City of Fresno. According to Ms. Yao, UMI moved out of the City of Fresno location because UMI's landlord threatened eviction proceedings. I am informed and believe that UMI was operating an illegal laboratory similar to the Reedley site. Ms. Yao further informed City staff that UMI filed for bankruptcy and that Prestige Biotech was UMI's largest creditor. However, it was not clear to

City staff who owns the biological material, mice and other personal property stored in the warehouse on the Property. City staff and Fresno County Public Health staff have not been able to identify or communicate with any representatives of UMI. Because Prestige is merely UMI's creditor and has yet to provide an order from a court of competent jurisdiction to exercise dominion and control over UMI's assets, Fresno County Public Health does not believe Prestige Biotech may lawfully claim ownership and control of the biological material or other personal property stored on the Property.

- 20. On April 4, 2023, the Court issued the Abatement Warrant to authorize the City to seize and humanely euthanize the mice.
- 21. On April 12, 2023, the City executed the Abatement Warrant along with the assistance of a veterinarian. Pursuant to the Abatement Warrant and upon confirmation that the mice were in distress, the veterinarian euthanized 773 mice. 178 mice were found to be already deceased at the time of execution of the Abatement Warrant.
- 22. On April 7, 2023, City staff communicated with Ms. Yao to provide reference to, and the need to comply with the California Medical Waste Management Act and use a licensed medical waste hauler, federal Hazardous Materials Regulations, and the APHIS permitting and the labeling and packing requirements to transport the viable biological material not deemed medical waste.
- 23. Based on the observations by City staff regarding the conditions of the building and materials stored therein, Fresno County Public Health sought to inspect the warehouse on the Property to evaluate and confirm hazardous materials, biological specimens stored on site, and the operational practices used by the operators to ensure hazardous waste and medical waste were appropriately being disposed in compliance with all applicable regulations and requirements.

Fresno County Public Health, State and Federal Investigation of Infectious Agents

24. On April 21, 2023, the Health Officer issued an Order of the Health Officer of the County of Fresno for the Inspection of Facility Located at 850 "I" Street, Reedley, California 93654 ("Inspection HOO"). The Inspection HOO was issued in response to the

operators' failure to communicate with Fresno County Health Department staff regarding the storage and usage of hazardous materials, biological specimens, and operational practices to ensure safe hazardous waste and medical waste disposal in compliance with Federal and State regulations. The Property, UMI and Prestige Biotech were not listed as a licensed laboratory under the Clinical Laboratory Improvement Amendments ("CLIA") under the federal Centers for Disease Control and Prevention. A demand for an inspection of the Property was necessary in response to the City's observations of the storage of reagents, biological samples, and containers used to culture viruses, and multiple chemical containers. Urgency for such an inspection was due to the City's noted substandard building conditions, specifically, the limited power source supplying refrigerators and freezers to store the biological materials, including containers that appeared to be used to culture viruses. Fresno County Public Health staff were concerned how the biological materials, viruses, bacterial agents, and other infectious agents may react if the refrigerators and freezers failed and these infectious agents reached an ambient temperature. Reasonable concerns existed as to the lack of safety measures in an unlicensed laboratory and its operations on the Property based on statements from the employees on site that they were conducting laboratory research on mice for COVID related applications and the City's documented inhumane treatment of these same mice. A true and correct copy of the Order of the Health Officer of the County of Fresno for the Inspection of Facility Located at 850 "I" Street, Reedley, California 93654 issued on April 21, 2023, is attached hereto as Exhibit A.

25. On April 21, 2023, Fresno County Public Health staff conducted an inspection of the Property pursuant to the Inspection HOO. During this inspection, Fresno County Public Health staff observed biologicals stored and kept in hazardous and non-compliant conditions, the presence of multiple infectious agents (confirmed by CDC) and pursuant to Title 17 California Code of Regulations Section 2500. Fresno County Public Health staff also observed the 32 refrigerators and freezers. A number of these refrigerators and freezers had either stopped functioning or were failing due to an inadequate power supply. This was due to the unpermitted electrical additions documented by City code enforcement during their inspections on March 3, 2023, and March 16, 2023.

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- 26. On April 25, 2023, Jerry Isaak, Chief of the City of Reedley Fire Department, issued a letter to Nicole Ziebra, City Manager of the City of Reedley, regarding the fire danger and explosion hazards created by the corrosive, toxic, and highly flammable chemicals stored within the warehouse on the Property. Chief Isaak stressed the need for a plan to have an evacuation zone of one city block around the warehouse on the Property. Given the fuel load of chemicals and manufacturing materials, Chief Isaak opined that this evacuation zone could likely increase. The proposed evacuation zone would include the City of Reedley Police Department, City Hall, the Kings Canyon Unified District main office, and approximately 12 residential homes. A true and correct copy of the letter dated April 25, 2023 from Jerry Isaak, Chief of the City of Reedley Fire Department, issued to Nicole Ziebra, City Manager of the City of Reedley, is attached hereto as **Exhibit B**.
- I am informed that on May 1, CDPH conducted a medical waste management investigatory inspection at the Property. I received a copy of the CDPH's letter dated May 9, 2023, to Xiuqin Yao, the President of Prestige Biotech, Inc., to summarize CDPH's investigation of medical waste management and the Department's May 1, 2023, inspection. During this inspection, CDPH staff observed 32 refrigerators and freezers. CDPH staff also observed several pieces of laboratory equipment, such as incubators and centrifuges. 30 of the 32 refrigerators and freezers were visually inspected. The two uninspected storage units were the -80C freezer and a refrigerators/freezer that CDPH staff was advised not to open due to biologicals stored within. In several freezers CDPH staff observed containers labeled as serum or plasma (of unknown origin) and/or with the name of an infectious agent. A substantial number of the containers were unlabeled and CDPH staff was unable to discern the contents of these containers. Many of the indecipherable containers appeared to contain blood, or a blood product, such as serum, or other bodily fluids. In several of the refrigerators and freezers, CDPH staff observed numerous vials of pharmaceuticals. CDPH referenced that all items at the Property that contain human blood or human blood fluids and all items that contain an infectious agent must be contained, labeled, stored, transported, treated, and disposed of as medical waste when these biological materials become waste per the requirements of the

Medical Waste Management Act ("MWMA"). CDPH also noted that any items that meet the definition of a "Regulated Waste" in the California Bloodborne Pathogen rule (Tile 8, California Code of Regulations, Section 5193) must be handled, stored, treated, and disposed as medical waste when they become waste. A true and correct copy of CDPH's letter dated May 9, 2023, to Xiuqin Yao, the President of Prestige Biotech, Inc., to summarize CDPH's investigation of medical waste management and the Department's May 1, 2023, inspection. is attached hereto as **Exhibit C.**

- 28. CDPH staff also observed what appeared to be a biohazardous waste container shrink wrapped to a pallet. The container was inaccessible due to safety concerns and CDPH staff was unable to inspect the container or its contents. This container appeared to have been moved from another location to this facility. CDPH staff also observed a wire metal storage rack with a box that contained one unused red biohazard autoclave bag and a box of unused orange biohazard autoclave bags. The red biohazard bag was not marked and certified. CDPH stated that Orange biohazard bags were not permissible for containment of medical waste in California. CDPH demanded that all waste inside a biohazardous container must be stored, transported, treated, and disposed of per the requirements of the MWMA.
- 29. Medical waste is required to be transported by a registered hazardous waste hauler. Medical waste may only be transported to a permitted medical waste treatment facility or transfer station or another registered generator for the purpose of consolidation before treatment and disposal. The latter transportation option is restricted to 35.2 pounds of medical waste and received facility is required to maintain documentation. Medical waste transported out of state must be consigned to a permitted medical waste treatment facility in the receiving state.
- 30. CDPH found that Prestige Biotech, Inc., is not registered with the CDPH as a medical waste generator. Registration and payment of the annual fee are required with the appropriate medical waste enforcement agency prior to the commencement of the generation of medical waste. CDPH is the appropriate medical waste enforcement agency for all medical waste generators in Fresno County. CDPH also found that Universal Meditech, Inc., was not

registered with CDPH as a medical waste generator.

- 31. I am informed that from May 2 through May 4, 2023, the CDC conducted an inspection of the Property.
- 32. From May 2 through May 4, 2023, staff from CDC's Division of Select Agents and Toxins inspected the Property along with staff from the City, Fresno County Public Health, CDPH, U.S. FDA, and FBI. CDC's staff inspected 33 storage units and reviewed the storage spaces held by Prestige Biotech inside the warehouse on the Property. The storage units inspected included: 2 ultralow temperature freezers (-80 and -60 degrees C) and 29 refrigerators/freezers (-20 degrees C). CDC staff also observed laboratory equipment as follows: 1 biological cabinet (last certified in 2009) and 1 floor model centrifuge. CDC staff observed thousands of vials that had unclear labeling, coded labeling, or no identification. There was evidence that the entity labeled items they believed to be dangerous. The 33 storage units were poorly organized and not all units were functional.
- 33. CDC staff determined that at least 20 potentially infectious agents of risk group 2 and risk group 3 were present as follows:
 - a. Potentially Infections bacterial agents present:
 - Chlamydia trachomatis
 - E. coli (recombinant strains)
 - Mycobacterium tuberculosis (Risk Group 3)
 - Mycoplasma pneumoniae and general Mycoplasma species
 - Neisseria meningitidis
 - Nostoc species
 - Sphingobacterium heparinum
 - Streptococcus pneumoniae and Streptococcus species
 - Toxoplasma gondii
 - b. Potentially Infections viral agents present:
 - Hepatitis B virus
 - Hepatitis C virus

- Dengue virus
- Human Immunodeficiency Virus 1 and 2
- Human Herpes virus 1 (Herpes simplex virus)
- Human Herpes virus 5 (Human Cytomegalovirus)
- Respiratory Syncytial virus
- Rubella virus
- Serve Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
 (Risk Group 3)
- c. Potentially Infectious parasites present:
 - Malaria (believed to be *P. falciparum* from Nigeria from the year 2000.
- 34. The CDC found the inventory (e.g., freezers and refrigerators) at the warehouse of Prestige Biotech is currently in storage and some material may not be stored in a safe manner. CDC recommended that if biological materials are located, local agencies should ensure professionals or subject matter experts move the inventory to ensure that there is no potential exposure to individuals or the environment.
- 35. Fresno County Public Health staff accompanied CDC staff during the inspection for infectious agents stored in the warehouse on the Property from May 2 through May 4, 2023. CDC staff communicated their concerns to Fresno County Public Health staff that the infectious agents listed above were stored in the warehouse on the Property.
- 36. I received a copy of the CDC's letter dated June 6, 2023, to summarize its support of California State Department of Health and the U.S. Food and Drug Administration during the Prestige Biotech Investigation. A true and correct copy of the CDC's letter dated June 6, 2023, is attached hereto as **Exhibit D**.
- 37. The Health Officer and Fresno County Public Health staff are gravely concerned about the storage of potentially infectious bacterial, viral, and parasitic agents present at the Property and the health and safety risk to the public by these infectious agents

May 31, 2023 Health Officer Order for Ordered Closure and Abatement

- 38. In response to the inspections by the City, CDPH, CDC and the Fresno County Public Health staff's own observations, the Health Officer issued Health Officer Order for County of Fresno to Close Business Operations and Abatement Biologicals Located at 850 "I" Street, Reedley, CA 93654 ("Second HOO"). On May 31, 2023, the Health Office issued the Second HOO to demand that the operators abate all biological materials stored in the warehouse on the Property. The Second HOO was issued as a result of the City's attempts at gathering authorized representatives contact information, repeated requests of complete lists of biologicals present, and an inspection pursuant to the Inspection HOO dated April 21, which revealed biologicals in hazardous and non-compliant conditions, the presence of multiple infectious agents, and multiple City building and fire code violations, including failing refrigeration, and documented out of compliance electrical additions, pest infestation, and to protect the public from the spread or exposure to the identified infectious agents found on the Property. The Second HOO was sent to the principals of Prestige Biotech, Inc. A true and correct copy of the Second HOO issued on May 31, 2023, is attached hereto as Exhibit E.
 - 39. The Second HOO demanded the Prestige Biotech undertake the following actions:
- a. "Within seven (7) days, the business located at <u>850 "I" Street, Reedley, CA 93654, Assessors Parcel Number 368-010-64S</u> ("Business") must produce the names, titles, and contact information of all persons authorized by law to conduct business and assume financial responsibility of the business in California. Such persons include corporate officers, directors, shareholders, or employees granted such abilities via board resolution." (Exh. D, Second HOO, 2.A.)
- b. "Within seven (7) days, the Business must produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State and local regulations. This plan should include transporters with appropriate licensures and certifications as well as a demonstration of commitment form these vendors via a purchase order or binding commitment. All biological specimens in non-operating refrigerators, or specimens that are improperly labeled or unidentified shall be treated as medical waste and abated and disposed of as medical waste. Such transporter contact information must be

 provided for the Fresno County Department of Public Health to verify." (Exh. D, Second HOO, 2.B.)

- 40. On May 31, 2023, the Second HOO was emailed to Xiuquin Yao, purported to be the President of Prestige Biotech; Michael Lin, UMI's bankruptcy attorney, and other emails purported to be associated with Prestige Biotech. Addition to service on Prestige Biotech and UMI representatives, the Second HOO was posted on the Fresno County Public Health's building located at 1221 Fulton Mall, Fresno, CA 93721; posted on the Fresno County Public Health's publicly available website; available upon request to any member of the public; and posted on the Property.
- 41. On June 3, 2023, David He, who purported to be a representative for Prestige Biotech and UMI, contacted me via email to respond to the Second HOO. My initial concern was that David He did not provide any documentation satisfactory to Fresno County Public Health that he was an authorized agent of either Prestige Biotech or UMI. Since Fresno County Public Health staff became aware of the illegal laboratory at the Property in December 2022, Fresno County Public Health staff has made repeated attempts to request the identities and contact information for the principals and/or authorized agents of Prestige Biotech and UMI. These attempts have thus far been futile. David He's communication similarly failed to provide the necessary documentation of authorization by Prestige Biotech and UMI that David He was an authorized agent. Thus, David He's communication failed to satisfy paragraph 2.A of the Second HOO.
- 42. David He's June 3, 2023, email also failed to provide an adequate biological abatement and disposal plan as required by paragraph 2.B of the Second HOO. First, David He proposed to use Dimension Waste Services ("Dimension") as Prestige Biotech's contractor to transport the biological material. However, Fresno County Public Health staff determined that Dimension did not have the required state and federal registration and certification to haul medical waste or transport infectious agents. Second, David He provided only an unsigned estimate from Dimension, which did not satisfy the requirement of the Second HOO of a binding commitment from such a contractor. Third, David He failed to provide any information on the

transportation and labeling of the infectious agents present on the Property in compliance with applicable Federal and State regulation of infectious agents and other biological material. I was deeply concerned with the desire to move the infectious agents to a purported new facility in the City of Fresno.

- 43. On June 5, 2023, I responded to David He's email, and included Xiuquin Yao, Michael Lin, and other emails purported to be associated with Prestige Biotech in my response. In my email response, I provided a point-by-point list of the deficiencies in David He's attempted response to the Second HOO. True and correct copies of my June 5, 2023, email response to David He's June 3, 2023 email are attached hereto as **Exhibit F.**
- 44. On June 7, 2023, David He responded via email to my June 5, 2023, communication detailing the deficiencies in the response to the Second HOO. In his latest response, David He stated that Prestige Biotech will prepare a board resolution to identify an authorized agent. However, I was taken aback by Mr. He's statement that he disputed that infectious agents were kept on the Property. A true and correct copy David He's June 7, 2023 email is attached hereto as Exhibit G.
- 45. On June 8, 2023, I responded to David He's June 7, 2023, email and provided a list of all identified infectious agents found on the Property. This list corresponds with the listed infections agents at *supra* paragraph 32 of this declaration. Mr. He's purported lack of knowledge of infectious agents on the Property raise serious concerns with the lack of safety protocols and direction offered by Prestige Biotech and other business entities handling of these infections agents as a serious threat to public health and safety.
- 46. In response to David He's communication in response to Second HOO and explanation to David He on the substantial deficiencies in Prestige Biotech's response and inadequate biological abatement and disposal plan, the Health Officer issued an amended health officer order to provide additional time for the Prestige Biotech to address the deficiencies.
- 47. On June 8, 2023, I sent an email correspondence to David He, Xiuquin Yao, Michael Lin, and other emails purported to be associated with Prestige Biotech to extend time for Prestige Biotech to respond to the health officer order for closure and abatement to June 11,

June 9, 2023 Amended Health Officer Order for Ordered Closure and Abatement

- 48. On June 9, 2023, the Health Officer issued Amended Health Officer Order for County of Fresno to Close Business Operations and Abatement Biologicals Located at 850 "I" Street, Reedley, CA 93654 ("Amended HOO") to demand that the Prestige Biotech abate all biological materials stored in the warehouse on the Property. TA true and correct copy of the Amended HOO issued on June 9, 2023, is attached hereto as **Exhibit H.**
- 49. The Amended HOO demanded the Prestige Biotech undertake the following actions:
- a. "By June 11, 2023, the business located at <u>850 "I" Street, Reedley, CA</u> <u>93654, Assessors Parcel Number 368-010-64S</u> ("Business") must produce the names, titles, and contact information of all persons authorized by law to conduct business and assume financial responsibility of the business in California. Such persons include corporate officers, directors, shareholders, or employees granted such abilities via board resolution." (Exh. H, Amended HOO, para. 2.A.)
- b. By June 11, 2023, the Business must produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State and local regulations. This plan should include transporters with appropriate licensures and certifications as well as a demonstration of commitment form these vendors via a purchase order or binding commitment. All biological specimens in non-operating refrigerators, or specimens that are improperly labeled or unidentified shall be treated as medical waste and abated and disposed of as medical waste. Such transporter contact information must be provided for the Fresno County Department of Public Health to verify. (Exh. H, Amended HOO, para. 2.B.)
- 50. The Amended HOO declared the storage of biologicals in an unsafe and unsanitary conditions constitutes a public nuisance. (Exh. H, Amended HOO, para. 4.)
- 51. On June 9, 2023, the Amended HOO was emailed to David He, Xiuquin Yao, Michael Lin, and other emails purported to be associated with Prestige Biotech. Addition to

service on Prestige and UMI representatives, the Amend HOO was posted on the Fresno County Public Health's building located at 1221 Fulton Mall, Fresno, CA 93721; posted on Fresno County Public Health's publicly available website; available upon request to any member of the public; and posted on the Property. A true and correct copy of my email dated June 9, 2023 to provide a copy of the Amended HOO to David He, Xiuquin Yao, Michael Lin, and other emails purported to be associated with Prestige Biotech is attached hereto as **Exhibit I**.

- 52. On June 9, 2023, David He responded to my email sent on June 8, 2023, where he again disputed that the identified infectious agents were found on the Property. Mr. He only conceded that UMI possessed recombinant *E. Coli* and disputed that the unlawful and unpermitted storage of biological materials on the Property presented a threat to public health.
- 53. On June 10, 2023, David He emailed me in response to the Amended HOO and provided the contact information for Xiuqin Yao and Xiaoxiao Wang, which included telephone numbers and addresses in China. However, this information failed to communicate and identify a representative for Prestige Biotech or UMI authorized to do business in California.
- 54. On June 10, 2023, I promptly responded to David He's email to inform him that Prestige and UMI have not complied with Amended HOO. In response to his demand to identify what information has not been provided, I responded and provided a point-by-point list of the deficiencies in Prestige Biotech's response to the Second HOO and Amended HOO. A true and correct copy of my email dated June 10, 2023 to David He is attached hereto as **Exhibit J.**
- 55. On June 13, 2023, I provided David He with a follow-up email to again state that Prestige Biotech and UMI have failed to comply with the requirements of the Second HOO and Amended HOO. In regard to paragraph 2.A of the Second HOO and Amended HOO, I explained that no viable California address was provided for the identified individual representatives. For example, UMI designated Xiaoxiao Wang as UMI's authorized agent to assume financial responsibility for the business operation at the Property. UMI listed 1320 E. Fortune Avenue, Suite 102, Fresno, California 93727 as Xiaoxiao Wang's address. The Fortune address in the City of Fresno is the same address that UMI previously operated its unlicensed laboratory that it hastily transferred the biologicals, laboratory equipment, and mice to the Property in Reedley

upon threats of eviction from the owner of the Fortune Avenue property. I contacted the owner of the Fortune Avenue property and he confirmed that UMI was not a tenant and that he previously took action to evict UMI. The other addresses provided for identified authorized agents were either empty offices or addresses in China that could not be verified. I further explained that the responses thus far failed to satisfy paragraph 2.B of the Second HOO and Amended HOO, and that Fresno County Public Health staff cannot communicate directly with any contractors retained by either Prestige Biotech and UMI, and that Fresno County Public Health must work directly through representatives of Prestige Biotech and/or UMI. Critically, Prestige Biotech and UMI failed to provide a biological abatement plan for the transport of the biologicals in compliance with applicable Federal, State, and local regulations. A true and correct copy of my follow-up email dated June 13, 2023 to David He is attached hereto as **Exhibit K**.

Prestige Biotech and UMI's Failure to Comply with Health Officer Orders

- 56. As of the date of this declaration, Prestige Biotech and UMI have failed to provide sufficient responses to the Second HOO and Amended HOO. Prestige Biotech and UMI have failed to provide a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State and local regulation; identify a registered and authorized medical waste hauler, and a plan to properly dispose of medical waste. Prestige Biotech's and UMI's time to comply with Amended HOO has lapsed.
- 57. The continued presence of biological material, medical waste, and infectious agents pose a serious and substantial risk to public health and safety. The failures by Prestige Biotech, its officers, directors, representatives and employees to employ adequate safety protocols as to the storage and disposal of these biological materials, medical waste, and infectious agents; the unsanitary and unsafe conditions of the warehouse including the unpermitted electrical additions and failure of the cold storage units; and infestation of pests create a dangerous environment and increases the likelihood of exposure to the surrounding community, residents of the City of Reedley, and the public at large to the infectious agents present and may result in the spread of these communicable diseases. For example, a mosquito could feed on a sample of tissue or blood exposed to Malaria stored on the Property and become

a vector to spread Malaria. Alternatively, the documented infestation of rats and other pests on the Property could become vectors if exposed to anyone of the numerous infectious agents that, as a matter of law, cause or significantly contributes to the cause of morbidity or mortality of human beings.

- As of the date of this declaration, Prestige Biotech and UMI have failed to take reasonable steps to abate the hazardous conditions on the Property and lawfully abate the biological material, medical waste and infectious agents found on the Property despite ample time to do so and numerous warnings and demands from local enforcement agencies. Furthermore, Prestige Biotech and UMI have failed to timely provide a sufficient response to the Second HOO and Amended HOO. The time to respond and take the required actions has passed. Prestige Biotech and UMI have failed and refused to lawfully abate the biological material, medical waste, and infectious agents. Thus, to seek any further consent to enter and abate from Prestige Biotech, UMI and other responsible parties would be futile.
- 59. The conditions described above are a threat to the health and safety of the occupants and surrounding community. The biological material, medical waste, and infectious agents are considered to be sources of infectious and communicable diseases for which the Health Officer is legally authorized to take any action to prevent the spread of such communicable diseases. Given the history of the poor maintenance of the Property and the unlawful storage and handling of biological materials, abatement by destruction of all biological material, medical waste and infectious agents is now the reasonable and prudent course of action to prevent the spread of the infectious and communicable diseases found on the Property.
- 60. The conditions described above are a threat to the health and safety of the public. These conditions violate Federal and State regulations regarding the storage, transport, and disposal of infectious agents. Fresno County Public Health staff and any of the County of Fresno's contractors must enter the Property to lawfully dispose of all biological material, medical waste, and infectious agents to abate the violations of Federal, State, and local law declared to be a public nuisance and prevent the potential spread of communicable diseases.
 - 61. Execution of this warrant and the abatement activity needed will require

coordination among the Fresno County Department of Public Health, Fresno County Administrative Office, Fresno County Sheriff's Office, Fresno County Office of County Counsel, the County's hired contractor, City of Reedley staff, City of Reedley Police Department and other participating state and federal agencies. This coordination and abatement work will be at a significant public cost and will require the marshalling of public resources. Any delays caused by the actions or inactions by the Owner, any occupants, or physical barriers on the Property will only result in the increase of this public cost and waste limited public resources.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct to the best of my knowledge.

Executed this /5 day of June 2023, in Fresno, California.

Humero Prado, declarant



County of Fresno

DEPARTMENT OF PUBLIC HEALTH

David Luchini, Director Dr. Rais Vohra, Interim Health Officer

ORDER OF THE HEALTH OFFICER OF THE COUNTY OF FRESNO FOR THE INSPECTION OF A FACILITY LOCATED AT 850 I STREET REEDLEY, CA 93654

April 21, 2023

Purusant to California Health and Safety Code Sections 120175.5 (b) & 101070 (b), the Health Officer of the County of Fresno orders as follows:

- 1. This order is issued as a result of multiple attempts to communicate with Universal MediTech Inc, Prestige Biotech Inc ("business owners") currently leasing space located at 850 I Street, Reedley, CA 93654 to confirm hazardous materials, biological specimens, and operational practices to ensure hazardous waste and medical waste are appropriately being disposed of in compliance with Federal and State requirements.
- 2. Attempts to communicate with business owners in regards to facility located at 850 I Street, Reedley, CA 93654 since December 19, 2022 from City of Reedley and other public agencies to ascertain contents and items at the facility have been unsucessful.
- 3. City of Reedley building officials posted on March 3, 2023 an Unsafe to Occupy Notice in front of the building. Building has limited power source supplying refrigerators and freezers that are storing reagents, biological samples, appearance of containers used to culture virus(es), and multiple chemical containers. Items documented by City of Reedley officials.
- 4. Preliminary investigation into the business owners does not list them as a licensed laboratory under Clinical Laboratory Improvement Amendments (CLIA) under the federal Centers for Disease Control and Prevention (CDC).
- 5. City of Reedley reports business owners statements that they are conducting laboratory research on mice for COVID.
- 6. City of Reedley has documented inhumane treatment of mice on site.
- 7. U.S. Food and Drug Administration (FDA) and California Department of Public Health, Food and Drug Branch (FDB) have been investigating the facility and business owners and have embargoed clinical testing kits at the facility due to non-compliance.
- 8. CDC has interest in the reagents being stored in the refrigerator/freezer that have been imported from outside of the United States which will require a federal permit which the business does not currently possess.

The Health Officer hereby orders an inspection, search, identification, and categorization of all chemicals, biological specimens, reagents, and other hazardous materials or biological materials to ascertain an inventory of items that may be a potential harm to the public if not handled and/or stored or transported appropriately in compliance with Federal and State regulations on April 21, 2023 and any necessary subsequent visits up to May 6, 2023.

I, as Interim Health Officer for the County of Fresno, encourage voluntary compliance with this Health Officer's Order. However, violation of this order is subject to fine, imprisonments or both (California Health and Safety Code Section 120295.)

Violation of or failure to comply with this Order is punishable by fine, imprisonment or both under various criminal statutes:

Cal. Penal Code section 148 makes it a misdemeanor to resist, delay, or obstruct a public officer, in the discharge of his or her duty. Sheriff deputies and city police officers are authorized to enforce health orders in the discharge of his or her duty.

Cal. Penal Code section 69 may be charged as a felony for the attempt, by means of any threat or violence, to deter or prevent an executive officer from performing any duty imposed by law, or to knowingly resist, by the use of force or violence, the officer, in the performance of the officer's duty. Sheriff deputies and city police officers are authorized to enforce health orders in the discharge of his or her duty.

Cal. Penal Code section 409.5 allows the health officer to close an area where a calamity has created an immediate menace to public health.

Copies of this Order shall promptly be (1) made available at the County of Fresno Department of Public Health office located at 1221 Fulton Mall, Fresno, CA 93721; and (2) provided to any member of the public requesting a copy of this Order.

Rais Vohra MD	4/21/2023
Rais Vohra, Fresno County Health Officer	Date of Issuance of Order

NOTICE OF RIGHTS

- 1. If you object to this order, you have a right to arrange for your own legal representative.
- 2. You have a right to also file for judicial relief to seek release from the order.
- 3. All requests to contact the County Health Officer will be through the Fresno County Department of Public Health at (559) 600-3332 during normal business hours. After hours, weekends, and holidays notify FCDPH On-Call staff at (559) 352-7067. If no response, contact County Sheriff Dispatch at (559) 600-3111.



REEDLEY FIRE DEPARTMENT FIRE ADMINISTRATION 1060 D STREET, REEDLEY CA 93654 JERRY ISAAK, CHIEF



April 25, 2023

TO: Nicole Zieba, City Manager

RE: 850 | Street

Hello Nicole,

I needed to inform you of the growing concern at 850 I Street. As the contractors hired by DTSC and Public Health proceed with inventorying the items on site, they are finding many of the unmarked chemicals stored in the warehouse are corrosive, toxic, and/or highly flammable. Due to the lack of proper labeling of containers, it is difficult to identify exactly what chemicals they are but can only provide information on their pH and flammability. The inventory list provided this am is helpful, but there are also drums of chemicals being stored in the warehouse with merchandise materials, various products and other miscellaneous equipment placed on top of the drums. This is not only limiting the access of the contractors to test and inventory the chemicals, but is also contributing to the large fuel load in the facility.

The refrigerators and freezers are still on and operating at this time and because of the hazardous (unpermitted) electrical present in the building, there is a huge concern for a fire to occur.

In the event a fire should occur, and due to the potential inhalation and explosion hazards, we are having to plan an evacuation zone of 1 city block around the structure. With the large fuel load of chemicals and manufacturing materials this evacuation zone could increase. The Fresno County Emergency Command Center has been advised that no entry will be made by firefighters if a fire were to occur at this site. Another concern that could increase the evacuation zone is the gas station located next to the warehouse.

Please note, this evacuation zone includes the City of Reedley Police Department, City of Reedley City Hall, the Kings Canyon Unified School District main office, and approximately 12 residential homes. All of the residential homes are older homes and are more than likely not equipped with fire sprinklers and could be at a higher risk for loss of life and/or property.

I cannot stress enough the importance of addressing the violations at 850 I St in a prompt manner. As the timeline of this investigation lengthens the more hazards to the public we identify, and the concern increased of a potential disaster for our city.

Sincerely,



State of California—Health and Human Services Agency California Department of Public Health



May 9, 2023

Ms. Xiuqin Yao President Prestige Biotech Inc. 850 I Street Reedley, CA 93654

c/o Zhaoyan Wang 4381 W Flamingo Road #5122 Las Vegas, NV 89103

MEDICAL WASTE MANAGEMENT INVESTIGATION OF PRESTIGE BIOTECH INC

Dear Ms. Yao:

On May 1, 2023, the California Department of Public Health, Medical Waste Management Program (Department) conducted a medical waste management investigatory inspection at the Prestige Biotech facility located at 850 "I" Street, Reedley, CA per California Health and Safety Code (HSC) Section 118335. The purpose of the Department's inspection was to ensure that the facility is in compliance with the requirements of the Medical Waste Management Act (MWMA). The observations and recommendations from the Department's investigation are provided below.

1. The visible contents of 30 of the 32 refrigerators and freezers at the facility were visually inspected. The two uninspected were the -80C freezer and a fridge/freezer that the Department was advised to not open due to the chemicals stored within. In several freezers the Department observed containers labeled as serum or plasma (of unknown origin) [example depicted in Figure A] and/or with the name of an infectious agent [example depicted in Figure B]. Many more containers were unlabeled or were labeled with indecipherable words or information. The Department was unable to discern the contents of these containers. Many of the indecipherable containers appeared to contain blood, or a blood product, such as serum, or another bodily fluid [example depicted in Figure



C]. In several of the refrigerators and freezers the Department observed numerous vials of pharmaceuticals [example depicted in Figure D]. The Department did not observe any item or container within the refrigerators or freezers clearly labeled as a waste.



Figure A.



Figure B.



Figure C.



Figure D.

- 2. All items at this facility that contain human blood or human blood fluids and all items that contain an infectious agent must be contained, labeled, stored, transported, treated, and disposed of as a medical waste when they become a waste. Additionally, any items at this facility that meet the definition of a medical waste when they become a waste must be properly contained, labeled, stored, transported, treated, and disposed of per the MWMA. A copy of the MWMA can be viewed on the Department's website:

 https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/MedicalWasteManagementAct.pdf.
- 3. For reference, "infectious agent" [HSC Section 117675] is defined in the MWMA as: a type of microorganism, bacteria, mold, parasite, or virus, including, but not limited to, organisms managed as Biosafety Level II, III, or IV by the federal Centers for Disease Control and Prevention, that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

Medical waste is defined in HSC Section 117690. For reference, subsection (a) states:

(a) "Medical waste" means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis. treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes. Biohazardous, pathology, pharmaceutical, sharps, and trace chemotherapy wastes that meet the conditions of this section are not subject to any of the hazardous waste requirements found in Chapter 6.5 (commencing with Section 25100) of Division 20.

- 4. In addition to the requirements of the MWMA, any items that meet the definition of a "Regulated Waste" in the California Bloodborne Pathogen rule (Title 8 California Code of Regulations, Section 5193) must be handled, stored, treated, and disposed of as a medical waste when they become a waste. A copy of the Bloodborne Pathogen rule can be viewed on the Department of Industrial Relation's website: https://www.dir.ca.gov/title8/5193.html.
- 5. The Department observed what appeared to be a biohazardous waste container shrink wrapped to a pallet that also held filing cabinets or storage shelves [Figure E]. The container was inaccessible due to safety concerns and the Department was unable to inspect the container or its contents, if any. This container appeared to have been moved from another location to this facility. All waste inside a biohazardous container must be stored, transported, treated, and disposed of per the requirements of the MWMA.



Figure E.

6. On a wire metal storage rack, the Department observed a box that contained one unused red biohazard autoclave bag and a box of unused orange biohazard autoclave bags [Figure F]. The red biohazard bag was not marked and certified. Orange biohazard bags are not permissible for containment of medical waste in California. The Department recommends disposal of the orange autoclave biohazard bags as a biohazardous waste to prevent alarm at solid waste facilities. See the HSC Section 117630 for more information regarding biohazard bags.



Figure F.

- 7. The Department did not observe a steam sterilizer (autoclave) at the facility; however, the presence of the autoclave bags may indicate the presence of an autoclave. The Department notes that onsite treatment of medical waste is permissible, but only after the autoclave is validated for efficacy under the Department's supervision and an onsite treatment permit has been issued. Prestige Biotech, Inc. does not have an onsite treatment permit issued by the Department. Pretreatment to inactivate infectious agents prior to disposal as a medical waste does not require a permit.
- 8. The Department observed several pieces of laboratory equipment, such as incubators and centrifuges [example depicted in Figure G]. This equipment could not be opened to examine the interior, so the contents, if any, are unknown. Given the appearance that all the items in the refrigerators and freezers were transported to the location while inside the refrigerators and freezers, the Department notes the possibility that there may be items that were transported inside of the laboratory equipment as well. As notated previously, if there are any contents that are to be disposed of and meet the definition of a medical waste, they must be properly contained, labeled, stored, transported, treated, and disposed of per the requirements of the MWMA.



Figure G.

- 9. Medical waste is required to be transported by a registered hazardous waste hauler. Medical waste may only be transported to a permitted medical waste treatment facility or transfer station or another registered generator for the purpose of consolidation before treatment and disposal. The latter transportation option is restricted to 35.2 pounds of medical waste and the receiving facility is required to maintain documentation. Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state.
- 10. Prestige Biotech Inc. is not registered with the Department as a medical waste generator. Registration and payment of the annual fee are required with the appropriate medical waste enforcement agency prior to the commencement of the generation of medical waste. The Department is the appropriate medical waste enforcement agency for all medical waste generators in Fresno County. Note that the associated facility, Universal Meditech Inc. (UMI), located at 1320 E Fortune Ave, Suite 102 Fresno, CA 93725 was not registered with the Department as a medical waste generator. However, a review of the hauling reports from medical waste haulers revealed that UMI generated medical waste. A map, list of medical waste enforcement agencies and pertinent contact information can be found on the Department's website:

https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Local-Enforcement-Agencies.aspx. The current fee schedule and generator application for the Department's enforcement areas, including Fresno County, may also be found on the Department's website:

 $\underline{https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Generators.aspx.}$

If you have any questions regarding the investigation report or require further assistance, please contact me at (916) 210-8533 or Thomas.Horner@cdph.ca.gov.

Sincerely,

Digitally signed by Thomas Horner Date: 2023.05.09 22:06:31 -07'00'

Thomas Horner

Senior Environmental Scientist - Supervisory Chief, Medical Waste Management Program

Ms. Xiuqin Yao May 9, 2023 Page 7

cc: David Luchini

Director

Fresno County Public Health Department

Joe Prado

Assistant Director

Fresno County Public Health Department

Nicole Zieba City Manager City of Reedley

Jesalyn Harper Code Enforcement Officer City of Reedley

Chris Pace

Environmental Program Manager II Chief, Environmental Management Branch

Sheetal Singh Environmental Program Manager I Chief, Emergency, Restoration and Waste Management Section

Dale Parks
Environmental Scientist
Inspector, Medical Waste Management Program



Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

June 6, 2023

CDC DSAT Support of the California State Department of Health and the U.S. Food and Drug Administration during the Prestige Biotech Investigation

REQUEST: On March 29, 2023, CDC was requested to provide onsite support of a joint investigation into Prestige Biotech. On April 21, 2023, CDC senior leadership requested that CDC's Division of Select Agents and Toxins (CDC/DSAT) lead CDC's response in the request for assistance from California's federal, state, and local partners. CDC/DSAT was asked to provide assistance to investigate the contents of numerous freezers at a warehouse owned by Prestige Biotech believed to hold biologics and possibly infectious materials, in violation of the Select Agent Regulations (42 CFR 73) and the Import Permit Regulations (42 CFR 71.54).

Entity Background and Overview

- Warehouse located at the intersection of I Street and 9th Street in Reedley, CA 93654 (see figure 1).
- The warehouse was found to have numerous building code violations as identified by the City of Reedley's Life Safety and Code Officer.
- During the initial investigation by the City of Reedley, it was found that there was laboratory equipment and the housing of laboratory mice within the warehouse.
- Prestige Biotech reportedly manufactured and distributed COVID-19 diagnostic tests in violation of U.S. Food and Drug Administration regulations (see figure 2)
 - o Animal housing room for mice (see figure 5)

Summary of CDC Onsite Support

Dates of Onsite Support: May 2-4, 2023

CDC Support Team:

- Von McClee, Branch Chief
- Thomas Cremer, Supervisory Microbiologist
- David Wang, Senior Microbiologist

Local, State and Federal Participants

- City of Reedley Jesalyn Harper (Onsite liaison)
- Fresno County Department of Public Health
- California Department of Public Health
- Food and Drug Administration
- Federal Bureau of Investigation

Observations

- CDC DSAT staff audited 33 storage units and reviewed the storage spaces held by Prestige Biotech inside the warehouse:
 - o Cold temperature Storage units (see figure 3)
 - 2 ultralow temperature freezers (-80 and -60 degrees C)
 - 29 refrigerators/freezers (-20 degrees C)
 - Laboratory equipment (see figure 4)
 - 1 biological safety cabinet Last certified in 2009
 - 1 floor model centrifuge

- Thousands of vials had unclear labeling, coded labeling, or no identifications (see figures 8-10).
 - 200 series samples are believed to be various recombinant *Escherichia coli* strains encoding for various antigens to make the diagnostic tests. The Prestige Biotech representative provided a limited key that was reported to contain proprietary or trade secret information. Various stocks of competent *E. coli* cells were found with these 200 series materials (see figures 11-12).
 - o 500 series samples were not identified and no key was provided.
- There was evidence that the entity labeled items they believe to be dangerous (see figure 13).
- The 33 storage units were poorly organized and not all units are functional (see figures 14-47)
- There was no evidence of select agents or toxins or evidence of non-compliance with 42 CFR 73.
- There was no conclusive evidence of violations of 42 CFR 71.54 for the importation of infections agents, substances or vectors. Some of the infectious agents could have come from Nigeria (*Plasmodium falciparum* from the year 2000) or Canada, but there were no import or shipping records available at the time of the visit.
- At least 20 potentially infectious agents of risk group 2 and risk group 3 agents were present (see figure 6).
 - Many agent stocks were provided by American Type Culture Collection (ATCC) based on the labeling present.
 - Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and *Mycobacterium tuberculosis* (RG3 agents) appears to be diagnostic specimens, not isolates or culture.

Potentially Infectious bacterial agents present:

- Chlamydia trachomatis
- E. coli (recombinant strains)
- Helicobacter pylori
- Mycobacterium tuberculosis (RG3)
- Mycoplasma pneumoniae and general Mycoplasma species, but no evidence of select agents
- Neisseria meningitidis
- *Nostoc* species
- Sphingobacterium heparinum
- Streptococcus pneumoniae and Streptococcus species
- Toxoplasma gondii

Potentially Infectious viral agents

- Hepatitis B virus
- Hepatitis C virus
- Dengue virus
- Human Immunodeficiency Virus 1 and 2
- Human Herpes virus 1 (Herpes simplex virus)
- Human Herpes virus 5 (Human Cytomegalovirus)
- Respiratory Syncytial virus
- Rubella virus
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (RG3)

Potentially Infectious parasites

• Malaria (believed to be *P. falciparum* from Nigeria from the year 2000)

Recommendations

- The California State Department of Health and the City of Reedley should consider requesting all records of importation for infectious agents:
 - Employees or owners of Prestige Biotech previously operated in Canada. During the move to the U.S., infectious material may have been imported into the U.S. Request clarification from the owner.
- The inventory (e.g., freezers and refrigerators) at the warehouse of Prestige Biotech is currently in storage and some material may not be stored in a safe manner. The California State Department of Health and the City of Reedley should ensure work only occurs in the warehouse once proper safety measures are in place. If the material is relocated, the California State Department of Health and the City of Reedley should ensure professionals or subject matter experts move the inventory to ensure there is no potential exposure to individuals or the environment.

CDC/DSAT will:

- Issue an Import Permit advisement letter to Prestige Biotech to ensure they know the Import Permit Regulations for importing infectious substances into the U.S.
- Add Prestige Biotech and associated entity names to the CDC Import Permit Program watch list
 in case the entity attempts to apply for a CDC Import Permit. If submitted, the application will be
 reviewed carefully, considering previous observations, and the program will inspect the facility
 before issuing any permit.
- Issue a Federal Select Agent Program advisement letter to Prestige Biotech informing them of the requirements for possession, use, and transfer of select agents and toxins if the entity decides to possess them.

Conclusion: Prestige Biotech or various owners of the materials present in the warehouse have yet to cooperate with document requests from multiple partner agencies fully. However, there is insufficient evidence at this time to conclude that there has been a violation of 42 CFR 71.54 or 42 CFR part 73.



County of Fresno

DEPARTMENT OF PUBLIC HEALTH

David Luchini, Director Dr. Rais Vohra, Interim Health Officer

Ordered Closure and Abatement

HEALTH OFFICER ORDER FOR COUNTY OF FRESNO TO CLOSE BUSINESS OPERATIONS AND ABATEMENT OF BIOLOGICALS LOCATED AT 850 "I" STREET, REEDLEY, CA 93654

Please read this Order carefully. Violations of or failure to comply with this Order is a crime punishable by fine, imprisonment, or both. Violators are also subject to civil enforcements actions including civil penalties of up to \$1,000 per violation per day, injunctive relief, and attorneys' fees and costs. (Health and Safety Code Section 120275; Penal Code Section 19; Government Code Section 25132.

Under the authority of California Health and Safety Code Section 120175, and 120275; Title 17 California Code of Regulations Section 2501; and Article XI of the California Constitution, The Health Officer of the County of Fresno ("Health Officer") Orders:

- 1. The business located at <u>850 "I" Street, Reedley, CA 93654, Assessors Parcel Number 368-010-648</u> ("Business") in the County of Fresno, whether public or private, and their ancillary use areas, which include but are not limited to parking areas, are hereby closed effective immediately and shall remain closed pending further Order of the Public Health Officer.
 - Entry to or use of Business, and their ancillary use areas, shall not be permitted by any person or group, regardless of membership status, admission cost, or party size.
- 2. This Order will permit the Fresno County Department of Public Health or its designee to abate all biologicals kept on premises of Business unless the following demands are met:
 - A. Within seven (7) days, the Business identified above must produce the names, titles, and contact information of all persons authorized by law to conduct business and assume financial responsibility of the Business in California. Such persons include corporate officers, directors, shareholders, or employees granted such abilities via board resolution.
 - B. Within seven (7) days, the Business identified above must produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State, and local regulations. This plan should include transporters with appropriate licensures and certifications as well as a demonstration of commitment from these vendors via a purchase order or binding commitment. All biological specimens in non-operating refrigerators, or specimens that are improperly labeled or unidentified shall be treated as medical waste and abated and disposed of as medical waste. Such transporters contact information must be provided for the Fresno County Department of Public Health to verify.
- 3. If the Fresno County Department of Public Health does not receive both of the above items or it does not approve the biological abatement plan, then they, or their designee, may immediately commence abatement of all biologicals found on the property.

- 4. This Order is issued as a result of the City of Reedley's attempts at gathering authorized representative contact information, repeated requests of complete lists of biologicals present, and an inspection pursuant to Health Officer Order dated April 21, 2023, which revealed biologicals in hazardous and non-compliant conditions, the presence of multiple infectious agents and pursuant to Title 17 California Code of Regulations Section 2500, and multiple City of Reedley building and fire code violations, including but not limited to, failing refrigeration, and documented out of compliance electrical additions.
- 5. Furthermore, the City of Reedley issued an Abatement Warrant on April 5, 2023, for the abatement of neglected laboratory mice, which revealed a persisting pest infestation at the premises.
- 6. This Order is issued based on evidence of increasing non-compliance with the City of Reedley by Business, and to protect the public from the risk of spread or of exposure to the identified infectious agents found on premises.
- 7. This order is made in accordance with all applicable State and Federal laws, including but not limited to: Health and Safety Code Sections 101030, et seq.: Health and Safety Code Sections 120100, et. Seq.; and Title 17 of the California Code of Regulations Section 2501.
- 8. To the extent necessary, pursuant to Government Code Sections 26602 and 41601 and Health and Safety Code Section 101029, the Health Officer requests that the Sheriff and all Chiefs of Police in the County ensure compliance with and enforcement of this Order. Violators are also subject to civil enforcement actions including civil penalties of up to \$1,000 per violation per day, injunctive relief, and attorneys' fees and costs.
- 9. Copies of this Order shall promptly be (1) made available at the County of Fresno Department of Public Health office located at 1221 Fulton Mall, Fresno, CA 93721; (2) posted on the County of Fresno Public Health Department's website; and (3) provided to any member of the public requesting a copy of this Order.

10. Language Assistance Rights

The contents of this letter involve your property and may impact your legal rights. Your response to this letter is very important, failure to respond may have legal consequences. If you need language assistance to understand the contents of this letter, please immediately contact the County of Fresno – Department of Public Health by phone at (559) 600-3200 or by email at dph@fresnocountyca.gov to be connected with a translator.

本函内容涉及您的财产,可能会影响您的合法权利。您对这封信的回复非常重要,未能回复可能会产生法律后果。如果您需要语言帮助来理解这封信的内容,请立即通过电话(559)600-3200或通过电子邮件 dph@fresnocountyca.gov与翻译人员联系弗雷斯诺县代码执行部门。

- 11. The following shall constitute the notice of rights:
 - a. If you object to this order, you have a right to arrange for your own legal representative.
 - b. You have a right to also file for judicial relief to seek release from the order.
 - c. All requests to contact the County Health Officer will be through FCDPH at (559) 600-3200 during normal business hours. After hours, weekends, and holidays notify FCDPH On-Call staff at (559) 352-7067. If no response, contact County Sheriff Dispatch at (559) 600-3111.

Rais Vohra MD	5/31/2023
(Signature of Health Officer or Deputy Health Officer)	(Date of Issuance of Order)

From: <u>Prado, Joe</u>

To: <u>davidmeditech@gmail.com</u>; <u>ml</u>; <u>clin</u>; <u>集团管理</u>; <u>prestibio2021@gmail.com</u>; <u>info.1320pbi</u>

Cc: Luchini, David; Vohra, Rais; Mendes, Vincent; Nicole.Zieba; Dhillon, Simranjit

Subject: RE: Second Fresno County Health Officer Order

Date: Monday, June 5, 2023 4:30:12 PM

Attachments: FW Mice care.msq

HO Closure Abatement Order 053123.pdf

image001.png

To All Representatives,

We have received and reviewed your response. The response is insufficient and does not meet the requirements set forth in the Health Officer Order dated 5-31-2023 (HOO). Thus actions will continue as stated in the HOO (attached). Here are the deficiencies in the email response from davidmeditech@gmail.com dated June 3rd, 2023 at 11:30pm (Email):

- 1. HOO Section 2.A. has not been complied to due to a Board resolution not being attached. Email attachment contained email statements only not a Board resolution. In addition Section 2.A. requested authorized individuals to conduct business in CA and persons that assume financial responsibilities. No documents presented addressed request in Section 2.A.
- 2. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction and is an assessment only. The plan does not speak to following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.
 - iii. Email number (2.), speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen contents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).
 - iv. In addition, Section 2.A. was not complied with thus this plan even if complete cannot be accepted.
 - b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor.

- 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor.
- b. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided.Binding commitment may be a purchase order or agreement with the vendor.
 - ii. In addition, Section 2.A. was not complied with thus even a signed agreement or purchase order would not comply with our request.

In accordance with the HOO, representatives have seven (7) days from receipt of HOO to provide the necessary documentation. The representatives have until June 7, 2023 to provide the County of Fresno additional documentation that meet the requirements set forth in HOO. The items noted above are based on documentation included in Email. If additional documentation is submitted for consideration please continue to do so as stated in HOO.

Thank you

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Saturday, June 03, 2023 11:30 PM

To: Prado, Joe <jprado@fresnocountyca.gov>

Cc: 集团管理 <jituanguanli@126.com>; ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>

Subject: Re: Second Fresno County Health Officer Order

CAUTION!!! - EXTERNAL EMAIL - THINK BEFORE YOU CLICK

Dear Joe Prado

I am David He. As a special representative, I am authorized to manage and deal with the related work of 850 temporary warehouse. Attachment 1 are the authorization documents for your reference.

In the previous period, I had good communication and cooperation with officials at all levels of the federal government, state government and municipal government, and has achieved phased results. After receiving your email and attachment order this Wednesday, we take it very seriously. After three days preparation, I give you a brief report on our previous and current work as following:

As for the disposal plan of 850 items, I sent a detail plan to the local municipal officer 10 days ago. Now I send you the plan officially again with updated information.

- 1. Background
- (1) Clean up and transfer of the goods in the 850 temporary warehouse as soon as possible to completely eliminate potential risks for fire and safety hazards. The finished diagnostic kits that have been identified will be destroyed.

- ②Government officials recommended good handling and destruction professional companies (Dimension Waste Services). Full service can be carried out according to the plan we have formulated, including warehouse clean up, fully licensed transportation and movement and destruction services.
- (3) The brand new Factory with 18,000 square feet building, located in 3900 N Blattella Ln. Fresno CA 93724, will be powered on around June 10th. The final city inspection will be completed within one or two week after that, and the occupancy permit will be issued. However, the final approval is subject to PBI obtain the license of biohazard. The lease contract are doing the final review.
- 2. Transfer all the refrigerators and freezers with the contents to the new site. Remove temporary electricity and water to completely eliminate the risk of fire and flood by listened electrician. This work will be completed around June 19-20.
- 3. Transfer potentially dangerous chemical reagents and solutions to the new site. Completely eliminate potential safety hazards for 850. This work will be completed around June 20-23.
- 4. PBI do the best to apply for the CDPH Medical Waste Registration License according to the regulation of the state government. Formal application documents and cheques have been sent by express mail on this Tuesday. A scanned copy of the full set of document in Attachment 2. We hope this license will be approved next week
- 5. If necessary, the isolation area in the new factory can be set up and the chemical and biological reagents with potential safety risks transported by 850 can be temporarily isolated and blocked by your department officer and waiting for further component confirmation or harmless inspection results.
- 6. Clean up and move general items and equipment. Those with value in use are moved to a new site, and those with no value in use are put into recycling trailers for recycling. This work will be completed around June 26-30th.
- 7. Disposal of embargoed finished products. Since most of the embargoed finished products are placed at the end of the temporary warehouse, it is necessary to wait until all the items are cleared and moved out before they can be shipped out for destruction. When all of these embargoed items are ready to be shipped, choose a suitable day to move out under the supervision of California government officials. This will be completed Early July.
- 8. I received a quote from Dimension company yesterday. Please see the quotation in Attachment 3 and 4 from this company. For this quotation, we have been discussing it over and over again this week with Ben, the manager in charge for this project. We have great confidence the Dimension company. They have full listens for the transportation, handling and destruction of chemical, biological and medical materials. We'd like to start the cooperation as soon as the price is confirmed.

Please give further advice after reviewing the above plan and arrangement. If you have any questions, please feel free to contact me. If possible, I would like to visit you at your office in afternoon of June 9. In this way, we can have a more in-depth discussion on many detailed technical issues and get your guidance. At the same time, I can submit a set of important documents regarding UMI chemical and biological reagents secure coding and labeling, so that you can have a more comprehensive and in-depth understanding of the biochemical and medical reagents stored in the refrigerator.

Best regard and have a nice weekend.

David He Representative for PBI/UMI TEL 909-682-9518

EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- Replied Message ----

From Prado, Joe<<a href="mailto:Joe<a href="mailto:JoePrado, Joe<|prado@fresnocountyca.gov

Date 05/31/2023 10:54

To davidmeditech@gmail.com、jituanguanli@126.com、prestibio2021@gmail.com、info.1320pbi

@gmail.com ml@linlawgroup.com clin@linlawgroup.com

Cc <u>Luchini, David<dluchini@fresnocountyca.gov>、Vohra, Rais<rvohra@fresnocountyca.gov>、Men</u>

des, Vincent<vmendes@fresnocountyca.gov>、Harper, Jesalyn<Jesalyn.Harper@reedley.ca.gov>

Nicola Ziaha, RaedleyeNicola Ziaha@reedley.ca.gov>、Dhillon, Simrapiit<

 $\begin{tabular}{ll} \searrow Nicole Zieba, Reedley < Nicole. Zieba@reedley. ca.gov > \searrow$ Dhillon, Simranjit < sidhillon@fresnocoun \\ \end{tabular}$

tyca.gov>

Subject Second Fresno County Health Officer Order

Good Morning Representatives,

I am delivering to you Fresno County's Health Officer Order. This second order requires action on your part within 7 days. Please submit all requested documentation to dph@fresnocountyca.gov within 7 days for County's review and consideration. There is a Notice of Rights included in the Order if you have further inquiries. Thank you



Joe Prado, Assistant Director Department of Public Health Tel: (559) 600-6402 jprado@fresnocountyca.gov This Email message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact the sender without using reply Email and destroy all copies of the original message.



From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Wednesday, June 07, 2023 2:53 PM **To:** Prado, Joe <iprado@fresnocountyca.gov>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>

Subject: 回复: Second Fresno County Health Officer Order

Dear Joe Predo

We will prepare the official document of the board resolution as soon as we receive your reply email on Monday. I have now received the documents from two companies. Please see the attachments.

At the same time, I have repeatedly communicated with the responsible manager of Dimension company. They have been working hard these two days to meet the requirements you put forward in the mail. They said they would email the file to me and maybe call you later this afternoon. They said that the time you gave was really too short because there are many factors involved in this project and there are different subcontracts involved and. It would be better to give an extension of two or three days.

Another very important key point is that 230531-HOO clearly mentioned the existence of Infectious Agents in the 850 temporary warehouse. We take this very seriously. Please give us the relevant findings and evidence as soon as possible. Because in the list of items and information we have, we have not get any infectious agents harmful to public health. We would be very grateful if you could pay special attention to this point.

If there is anything else I can help, please feel free to contact me.

Sincerely yours

David He Representative for PBI/UMI TEL 909-682-9518

EMAIL <u>davidmeditech@gmail.com</u>



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- 回复的原邮件 ----

发件人 Prado. Joe<iprado@fresnocountvca.gov>

日期 2023年06月05日 16:28

收件人 <u>davidmeditech@gmail.com</u>、<u>ml<ml@linlawgroup.com></u>、<u>clin<clin@linlawgroup.com></u>、<u>集团管</u>

理<iituanguanli@126.com>、prestibio2021@gmail.com、info.1320pbi<info.1320pbi@gmail.com

 \geq

抄送至 <u>Luchini, David<dluchini@fresnocountyca.gov>、Vohra, Rais<rvohra@fresnocountyca.gov>、Men</u>

des, Vincent<vmendes@fresnocountyca.gov>、Nicole.Zieba<Nicole.Zieba@reedley.ca.gov>、Dhil

lon, Simranjit<sidhillon@fresnocountyca.gov>

主题 RE: Second Fresno County Health Officer Order

To All Representatives,

We have received and reviewed your response. The response is insufficient and does not meet the requirements set forth in the Health Officer Order dated 5-31-2023 (HOO). Thus actions will continue as stated in the HOO (attached). Here are the deficiencies in the email response from davidmeditech@gmail.com dated June 3rd, 2023 at 11:30pm (Email):

- 1. HOO Section 2.A. has not been complied to due to a Board resolution not being attached. Email attachment contained email statements only not a Board resolution. In addition Section 2.A. requested authorized individuals to conduct business in CA and persons that assume financial responsibilities. No documents presented addressed request in Section 2.A.
- 2. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction and is an assessment only. The plan does not speak to

- following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.
- iii. Email number (2.), speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen contents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).
- iv. In addition, Section 2.A. was not complied with thus this plan even if complete cannot be accepted.
- b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor.
 - 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor.
- c. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.
 - ii. In addition, Section 2.A. was not complied with thus even a signed agreement or purchase order would not comply with our request.

In accordance with the HOO, representatives have seven (7) days from receipt of HOO to provide the necessary documentation. The representatives have until June 7, 2023 to provide the County of Fresno additional documentation that meet the requirements set forth in HOO. The items noted above are based on documentation included in Email. If additional documentation is submitted for consideration please continue to do so as stated in HOO.

Thank you

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Saturday, June 03, 2023 11:30 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: 集团管理 < iituanguanli@126.com > ; ml < ml@linlawgroup.com > ; clin < clin@linlawgroup.com > ; Luchini, David < dluchini@fresnocountyca.gov > ; Vohra, Rais < rvohra@fresnocountyca.gov > ; Mendes, Vincent < red < vmendes@fresnocountyca.gov > ; Nicole.Zieba < Nicole.Zieba@reedley.ca.gov > ; Dhillon, Simranjit < sidhillon@fresnocountyca.gov >

CAUTION!!! - EXTERNAL EMAIL - THINK BEFORE YOU CLICK

Dear Joe Prado

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Best regard and have a nice weekend.

David He Representative for PBI/UMI TEL 909-682-9518

EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: davidmeditech@gmail.com

---- Replied Message ----

From Prado, Joe<iprado@fresnocountyca.gov>

Date 05/31/2023 10:54

To <u>davidmeditech@gmail.com</u>, <u>jituanguanli@126.com</u>, <u>prestibio2021@gmail.com</u>, <u>info.1320pbi</u>

@gmail.com、 ml@linlawgroup.com、 clin@linlawgroup.com

Cc <u>Luchini, David<dluchini@fresnocountyca.gov></u>, <u>Vohra, Rais<rvohra@fresnocountyca.gov></u>, <u>Men</u>

des, Vincent<vmendes@fresnocountyca.gov>、Harper, Jesalyn<Jesalyn.Harper@reedley.ca.gov>

Nicole Zieba, Reedley<Nicole.Zieba@reedley.ca.gov> Dhillon, Simranjit<sidhillon@fresnocoun tvca.gov>

Subject Second Fresno County Health Officer Order

Good Morning Representatives,

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Joe Prado, Assistant Director Department of Public Health Tel: (559) 600-6402 jprado@fresnocountyca.gov

This Email message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact the sender without using reply Email and destroy all copies of the original message.



County of Fresno DEPARTMENT OF PUBLIC HEALTH

Amended 6-9-2023

Ordered Closure and Abatement

HEALTH OFFICER ORDER FOR COUNTY OF FRESNO TO CLOSE BUSINESS OPERATIONS AND ABATEMENT OF BIOLOGICALS LOCATED AT 850 "I" STREET, REEDLEY, CA 93654

Please read this Order carefully. Violations of or failure to comply with this Order is a crime punishable by fine, imprisonment, or both. Violators are also subject to civil enforcements actions including civil penalties of up to \$1,000 per violation per day, injunctive relief, and attorneys' fees and costs. (Health and Safety Code Section 120275; Penal Code Section 19; Government Code Section 25132.

Under the authority of California Health and Safety Code Section 120175, and 120275; Title 17 California Code of Regulations Section 2501; and Article XI of the California Constitution, The Health Officer of the County of Fresno ("Health Officer") Orders:

1. The business located at <u>850 "I" Street, Reedley, CA 93654, Assessors Parcel Number 368-010-64S</u> ("Business") in the County of Fresno, whether public or private, and their ancillary use areas, which include but are not limited to parking areas, are hereby closed effective immediately and shall remain closed pending further Order of the Public Health Officer.

Entry to or use of Business, and their ancillary use areas, shall not be permitted by any person or group, regardless of membership status, admission cost, or party size.

- 2. This Order will permit the Fresno County Department of Public Health or its designee to abate all biologicals kept on premises of Business unless the following demands are met:
 - A. By June 11, 2023, the Business identified above must produce the names, titles, and contact information of all persons authorized by law to conduct business and assume financial responsibility of the Business in California. Such persons include corporate officers, directors, shareholders, or employees granted such abilities via board resolution.
 - B. By June 11, 2023, the Business identified above must produce a biological abatement and disposal plan for the transport of properly labeled and identified biological specimens consistent with Federal, State, and local regulations. This plan should include transporters with appropriate licensures and certifications as well as a demonstration of commitment from these vendors via a purchase order or binding commitment. All biological specimens in non-operating refrigerators, or specimens that are improperly labeled or unidentified shall be treated as medical waste and abated and disposed of as medical waste. Such transporters contact information must be provided for the Fresno County Department of Public Health to verify.
- 3. If the Fresno County Department of Public Health does not receive both of the above items or it does not approve the biological abatement plan, then they, or their designee, may immediately commence abatement of all biologicals found on the property.

Promotion, preservation and protection of the community's health

1221 Fulton Street /P. O. Box 11867, Fresno, CA 93775 (559) 600-3200 FAX (559) 600-7687

The County of Fresno is an Equal Employment Opportunity Employer www.co.fresno.ca.us www.fcdph.org

- 4. This Order is issued as a result of the City of Reedley's attempts at gathering authorized representative contact information, repeated requests of complete lists of biologicals present, and an inspection pursuant to Health Officer Order dated April 21, 2023, which revealed biologicals in hazardous and non-compliant conditions, the presence of multiple infectious agents and pursuant to Title 17 California Code of Regulations Section 2500, and multiple City of Reedley building and fire code violations, including but not limited to, failing refrigeration, and documented out of compliance electrical additions. The storage of biologicals in unsafe and unsanitary conditions constitutes a public nuisance.
- 5. Furthermore, the City of Reedley issued an Abatement Warrant on April 5, 2023, for the abatement of neglected laboratory mice, which revealed a persisting pest infestation at the premises.
- 6. This Order is issued based on evidence of increasing non-compliance with the City of Reedley by Business, and to protect the public from the risk of spread or of exposure to the identified infectious agents found on premises.
- 7. This order is made in accordance with all applicable State and Federal laws, including but not limited to: Health and Safety Code Sections 101030, et seq.: Health and Safety Code Sections 120100, et. Seq.; and Title 17 of the California Code of Regulations Section 2501.
- 8. To the extent necessary, pursuant to Government Code Sections 26602 and 41601 and Health and Safety Code Section 101029, the Health Officer requests that the Sheriff and all Chiefs of Police in the County ensure compliance with and enforcement of this Order. Violators are also subject to civil enforcement actions including civil penalties of up to \$1,000 per violation per day, injunctive relief, and attorneys' fees and costs.
- 9. Copies of this Order shall promptly be (1) made available at the County of Fresno Department of Public Health office located at 1221 Fulton Mall, Fresno, CA 93721; (2) posted on the County of Fresno Public Health Department's website; and (3) provided to any member of the public requesting a copy of this Order.

10. Language Assistance Rights

The contents of this letter involve your property and may impact your legal rights. Your response to this letter is very important, failure to respond may have legal consequences. If you need language assistance to understand the contents of this letter, please immediately contact the County of Fresno – Department of Public Health by phone at (559) 600-3200 or by email at dph@fresnocountyca.gov to be connected with a translator.

本函内容涉及您的财产,可能会影响您的合法权利。您对这封信的回复非常重要,未能回复可能会产生法律后果。如果您需要语言帮助来理解这封信的内容,请立即通过电话(559)600-3200或通过电子邮件 dph@fresnocountyca.gov与翻译人员联系弗雷斯诺县代码执行部门。

- 11. The following shall constitute the notice of rights:
 - a. If you object to this order, you have a right to arrange for your own legal representative.
 - b. You have a right to also file for judicial relief to seek release from the order.
 - c. All requests to contact the County Health Officer will be through FCDPH at (559) 600-3200 during normal business hours. After hours, weekends, and holidays notify FCDPH On-Call staff at (559) 352-7067. If no response, contact County Sheriff Dispatch at (559) 600-3111.

Rais Volper MD	6/9/2023
(Signature of Health Officer or Deputy Health Officer)	(Date of Issuance of Order)

From: Prado, Joe
To: He David

Cc: ml; clin; 集团管理; info.1320pbi; Luchini, David; Vohra, Rais; Mendes, Vincent; Nicole.Zieba; Dhillon, Simranjit;

prestibio2021

Subject: RE: 回复: Second Fresno County Health Officer Order

Date: Friday, June 9, 2023 8:47:45 PM
Attachments: AmendedFresnoCountyHOO6-9-23.pdf

David.

I'm attaching a further amended Health Officer Order dated 6-9-23.

To date, PBI/UMI have failed to provide an adequate response to the Health Officer Order. We direct you to the Health Officer Order and the need to comply with all of this Order's requirements by June 11, 2023. The presence of infectious agents at the 850 I Street warehouse is beyond dispute. Additionally please provide updated addresses and phone numbers of Xiaoxiao Wang and Xiuqin Yao.

From: He David <davidmeditech@gmail.com>

Sent: Friday, June 09, 2023 12:45 PM

To: Prado, Joe < jprado@fresnocountyca.gov>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>

Subject: Re: 回复:Second Fresno County Health Officer Order

Dear Joe Prado

Your email of yesterday evening has been received. Thank you very much for giving us an extension to June 11.

After receiving your email, I immediately forwarded it to Dimension manager in charge. We had a telephone discussion this morning. He had been calling you several times, but couldn't get through. We are particularly concerned about now is what documents need to be supplemented. You'd better give us a detailed explanation.

The important is whether your department can accept Dimension as the General Contractor for transportation and clearance and destruction of this project. If you agree, please give us a written reply ASAP, so we can plan all the details we need to work together for the further operation. If you think this company is not good enough, then we need to looking for another company quickly, so we need more time to extend.

More importantly, you mentioned in the email that Finding and Evidence of infectious agents in the email on April 7. I did not receive this email, and I also consulted the relevant people, but no one receive such email either. They said the email received on April 7 was sent by Ms.Harper, which only

gave explanation and four attachments for guidance of State Regulation and Transportation Reference. Therefore, you still haven't give the solid evidence about the infectious agents. If you have more information, please send to me immediately. We pay special attention to this, which is also closely related to the detailed further operation of the items in the 850 temporary warehouse.

After I told the former staff about the infectious agents in your email, all of them are very surprise. There must be a huge misunderstanding because the infectious agents you mentioned have never been exposed in UMI research and production except recombinant E. coli, which is commonly used in most biological laboratories, and it will certainly not have any impact on public health. I did not see any similar infectious agents in the list of all items and refrigerator contents provided by UMI. Please provide all the information you have today, so we can continue to hard work over the weekend and reply to you on Monday to meet your order deadline of June 11.

Thank you very much for your special attention.

David He
Representative for PBI/UMI
TEL 909-682-9518
EMAIL davidmeditech@gmail.com

Prado, Joe < iprado@fresnocountyca.gov> 于 2023年6月8日周四 19:37写道:

To All Representatives,

I'm attaching a Revised Health Officer Order that has provided additional time, till June 11, 2023 to complete providing the missing documentation requested in the Health Officer Order dated 5-31-2023 and Revised Order dated 6-8-2023.

Your email dated June 7, 2023 requested our findings related to infectious agents. The items listed below is only an example of the infectious agents found onsite and is not a complete exhaustive list:

Chlamydia trachomatis

E. coli (recombinant strains)

Helicobacter pylori

Mycoplasma pneumoniae and general Mycoplasma species

Neisseria meningitidis

Nostoc species

Sphingobacterium heparinum

Streptococcus pneumoniae Streptococcus species

Toxoplasma gondii

Hepatitis B virus

Hepatitis C virus

Dengue virus

Human Immunodeficiency Virus 1 and 2

Human Herpes virus 1 Human Herpes virus 5 Respiratory Syncytial virus Rubella virus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (RG3)

The infectious agents fall under the packaging and shipping requirements included in correspondence provided on April 7, 2023.

Please provide the remaining documentation by June 11, 2023.

From: <u>davidmeditech@gmail.com</u> < <u>davidmeditech@gmail.com</u>>

Sent: Wednesday, June 07, 2023 2:53 PM **To:** Prado, Joe <<u>iprado@fresnocountyca.gov</u>>

Cc: ml <<u>ml@linlawgroup.com</u>>; clin <<u>clin@linlawgroup.com</u>>; 集团管理 <<u>jituanguanli@126.com</u>>; info.1320pbi</<u>info.1320pbi@gmail.com</u>>; Luchini, David <<u>dluchini@fresnocountyca.gov</u>>; Vohra, Rais <<u>rvohra@fresnocountyca.gov</u>>; Mendes, Vincent <<u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba <<u>Nicole.Zieba@reedley.ca.gov</u>>; Dhillon, Simranjit <<u>sidhillon@fresnocountyca.gov</u>>

Subject: 回复: Second Fresno County Health Officer Order

Dear Joe Predo

We will prepare the official document of the board resolution as soon as we receive your reply email on Monday. I have now received the documents from two companies. Please see the attachments.

At the same time, I have repeatedly communicated with the responsible manager of Dimension company. They have been working hard these two days to meet the requirements you put forward in the mail. They said they would email the file to me and maybe call you later this afternoon. They said that the time you gave was really too short because there are many factors involved in this project and there are different subcontracts involvedand. It would be better to give an extension of two or three days.

Another very important key point is that 230531-HOO clearly mentioned the existence of Infectious Agents in the 850 temporary warehouse. We take this very seriously. Please give us the relevant findings and evidence as soon as possible. Because in the list of items and information we have, we have not get any infectious agents harmful to public health. We would be very grateful if you could pay special attention to this point.

If there is anything else I can help, please feel free to contact me.

Sincerely yours

David He



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- 回复的原邮件 ----

发件人 <u>Prado, Joe<iprado@fresnocountyca.gov></u>

日期 2023年06月05日 16:28

收件人 <u>davidmeditech@gmail.com</u>、<u>ml<ml@linlawgroup.com</u>>、<u>clin<clin@linlawgroup.com</u>>、<u>集团</u>

管理<jituanguanli@126.com>、prestibio2021@gmail.com、info.1320pbi<info.1320pbi@gmail

l.com>

抄送至 Luchini, David<dluchini@fresnocountyca.gov>、Vohra, Rais<ryohra@fresnocountyca.gov>、M

endes, Vincent<vmendes@fresnocountyca.gov>、Nicole.Zieba<Nicole.Zieba@reedley.ca.gov>

Dhillon, Simranjit<sidhillon@fresnocountyca.gov>

主题 RE: Second Fresno County Health Officer Order

To All Representatives,

We have received and reviewed your response. The response is insufficient and does not meet the requirements set forth in the Health Officer Order dated 5-31-2023 (HOO). Thus actions will continue as stated in the HOO (attached). Here are the deficiencies in the email response from davidmeditech@gmail.com dated June 3rd, 2023 at 11:30pm (Email):

- 1. HOO Section 2.A. has not been complied to due to a Board resolution not being attached. Email attachment contained email statements only not a Board resolution. In addition Section 2.A. requested authorized individuals to conduct business in CA and persons that assume financial responsibilities. No documents presented addressed request in Section 2.A.
- 2. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction and is an assessment only.

The plan does not speak to following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.

- iii. Email number (2.), speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen contents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).
- iv. In addition, Section 2.A. was not complied with thus this plan even if complete cannot be accepted.
- b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor.
 - 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor.
- c. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.
 - ii. In addition, Section 2.A. was not complied with thus even a signed agreement or purchase order would not comply with our request.

In accordance with the HOO, representatives have seven (7) days from receipt of HOO to provide the necessary documentation. The representatives have until June 7, 2023 to provide the County of Fresno additional documentation that meet the requirements set forth in HOO. The items noted above are based on documentation included in Email. If additional documentation is submitted for consideration please continue to do so as stated in HOO.

From: <u>davidmeditech@gmail.com</u> < <u>davidmeditech@gmail.com</u>>

Sent: Saturday, June 03, 2023 11:30 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: 集团管理 < jituanguanli@126.com >; ml < ml@linlawgroup.com >; clin < clin@linlawgroup.com >; Luchini, David < dluchini@fresnocountyca.gov >; Vohra, Rais < rvohra@fresnocountyca.gov >; Mendes, Vincent < vmendes@fresnocountyca.gov >; Nicole.Zieba < Nicole.Zieba@reedley.ca.gov >;

Dhillon, Simranjit < sidhillon@fresnocountyca.gov>

Subject: Re: Second Fresno County Health Officer Order

CAUTION!!! - EXTERNAL EMAIL - THINK BEFORE YOU CLICK

Dear Joe Prado

I am David He. As a special representative, I am authorized to manage and deal with the related work of 850 temporary warehouse. Attachment 1 are the authorization documents for your reference.

In the previous period, I had good communication and cooperation with officials at all levels of the federal government, state government and municipal government, and has achieved phased results. After receiving your email and attachment order this Wednesday, we take it very seriously. After three days preparation, I give you a brief report on our previous and current work as following:

As for the disposal plan of 850 items, I sent a detail plan to the local municipal officer 10 days ago. Now I send you the plan officially again with updated information.

- 1. Background
- ① Clean up and transfer of the goods in the 850 temporary warehouse as soon as possible to completely eliminate potential risks for fire and safety hazards. The finished diagnostic kits that have been identified will be destroyed.
- ②Government officials recommended good handling and destruction professional companies (Dimension Waste Services). Full service can be carried out according to the plan we have formulated, including warehouse clean up, fully licensed transportation and movement and destruction services.
- (3) The brand new Factory with 18,000 square feet building, located in 3900 N Blattella Ln. Fresno CA 93724, will be powered on around June 10th. The final city inspection will be completed within one or two week after that, and the occupancy permit will be issued. However, the final approval is subject to PBI obtain the license of biohazard. The lease contract are doing the final review.
- 2. Transfer all the refrigerators and freezers with the contents to the new site. Remove temporary electricity and water to completely eliminate the risk of fire and flood by listened electrician. This work will be completed around June 19-20.
- 3. Transfer potentially dangerous chemical reagents and solutions to the new site. Completely eliminate potential safety hazards for 850. This work will be completed around June 20-23.
- 4. PBI do the best to apply for the CDPH Medical Waste Registration License according to the regulation of the state government. Formal application documents and cheques have been sent

by express mail on this Tuesday. A scanned copy of the full set of document in Attachment 2. We hope this license will be approved next week

- 5. If necessary, the isolation area in the new factory can be set up and the chemical and biological reagents with potential safety risks transported by 850 can be temporarily isolated and blocked by your department officer and waiting for further component confirmation or harmless inspection results.
- 6. Clean up and move general items and equipment. Those with value in use are moved to a new site, and those with no value in use are put into recycling trailers for recycling. This work will be completed around June 26-30th.
- 7. Disposal of embargoed finished products. Since most of the embargoed finished products are placed at the end of the temporary warehouse, it is necessary to wait until all the items are cleared and moved out before they can be shipped out for destruction. When all of these embargoed items are ready to be shipped, choose a suitable day to move out under the supervision of California government officials. This will be completed Early July.
- 8. I received a quote from Dimension company yesterday. Please see the quotation in Attachment 3 and 4 from this company. For this quotation, we have been discussing it over and over again this week with Ben, the manager in charge for this project. We have great confidence the Dimension company. They have full listens for the transportation, handling and destruction of chemical, biological and medical materials. We'd like to start the cooperation as soon as the price is confirmed.

Please give further advice after reviewing the above plan and arrangement. If you have any questions, please feel free to contact me. If possible, I would like to visit you at your office in afternoon of June 9. In this way, we can have a more in-depth discussion on many detailed technical issues and get your guidance. At the same time, I can submit a set of important documents regarding UMI chemical and biological reagents secure coding and labeling, so that you can have a more comprehensive and in-depth understanding of the biochemical and medical reagents stored in the refrigerator.

Best regard and have a nice weekend.

David He
Representative for PBI/UMI
TEL 909-682-9518
EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- Replied Message ----

From <u>Prado, Joe<jprado@fresnocountyca.gov></u>

Date 05/31/2023 10:54

To <u>davidmeditech@gmail.com</u>, <u>jituanguanli@126.com</u>, <u>prestibio2021@gmail.com</u>, <u>info.1320p</u>

bi@gmail.com, ml@linlawgroup.com, clin@linlawgroup.com

Cc <u>Luchini, David<dluchini@fresnocountyca.gov></u>, <u>Vohra, Rais<rvohra@fresnocountyca.gov></u>, <u>M</u>

endes, Vincent<vmendes@fresnocountyca.gov>、Harper, Jesalyn<Jesalyn.Harper@reedley.ca.gov>、Nicole Zieba, Reedley<Nicole.Zieba@reedley.ca.gov>、Dhillon, Simranjit<sidhillon@fres

nocountyca.gov>

Subject Second Fresno County Health Officer Order

Good Morning Representatives,

I am delivering to you Fresno County's Health Officer Order. This second order requires action on your part within 7 days. Please submit all requested documentation to dph@fresnocountyca.gov within 7 days for County's review and consideration. There is a Notice of Rights included in the Order if you have further inquiries. Thank you



Joe Prado, Assistant Director Department of Public Health Tel: (559) 600-6402 jprado@fresnocountyca.gov

This Email message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact the sender without using reply Email and destroy all copies of the original message.

 From:
 Prado, Joe

 To:
 He David

Cc: ml; clin; 集团管理; info.1320pbi; Luchini, David; Vohra, Rais; Mendes, Vincent; Nicole.Zieba; Dhillon, Simranjit;

prestibio2021

Subject: RE: 回复: Second Fresno County Health Officer Order

Date: Saturday, June 10, 2023 3:11:04 PM

David,

Health Officer Order Section 2.A. – I am waiting for County Counsel to decide whether or not the additional information submitted today was sufficient.

Health Order Section 2.B. -

- 1. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction and is an assessment only. The plan does not speak to following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.
 - 1. No plan has been submitted packaging and shipping of infectious agents and the protocols that will be followed.
 - 2. The attachment from Dimension speaks more to disposal and assessment. This plan is sufficient for disposal only.
 - iii. Email from David He speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen infectious agents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements as a sufficient plan for packaging and shipping of infectious agents. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).
 - b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor. Initial subcontractor proposed had an expired certificate.
 - 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor. No packaging and shipping certification of infectious agents have been provided or a

plan on transporting infectious agents.

- b. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.

From: He David <davidmeditech@gmail.com>

Sent: Saturday, June 10, 2023 2:28 PM

To: Prado, Joe < iprado@fresnocountyca.gov>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>; prestibio2021 cprestibio2021@gmail.com>

Subject: Re: 回复: Second Fresno County Health Officer Order

Hello Joe

Could you clearly indicate what other documents have not been provided? David

Prado, Joe < <u>iprado@fresnocountyca.gov</u>> 于 2023年6月10日周六 13:59写道:

To All Representatives,

The Health Officer has not been complied with. Previous email noted the discrepancies and there are still outstanding documentation.

Sent via the Samsung Galaxy S21+ 5G, an AT&T 5G smartphone Get <u>Outlook for Android</u>

From: He David <<u>davidmeditech@gmail.com</u>> Sent: Saturday, June 10, 2023 12:52:05 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>; prestibio2021 prestibio2021@gmail.com>

Subject: Re: 回复: Second Fresno County Health Officer Order

Hello Joe

Thank you very much for your reminder. The addresses and telephone numbers of Xiaoxiao Wang and Xiuqin Yao are updated information as following:

Xiuqin Yao

87 Zhuzhou Road, Nancun Town, Qingdao City, Shandong Province, China.

Tel: 18661707755

Xiaoxiao Wang

404 Wanggezhuang Street, Laoshan District, Qingdao City, Shandong

Province, China Tel: 13255326066

The official registered address of the company has been listed in the Letter of Board Resolution from both company.

Universal Meditech has formally hired a representative lawyer this year, and the contact information is as follows:

Michael M. Lin, D.C., Esq.

Lin Law Group, P.C. 5288 Spring Mtn. Rd.

Suite 103

Las Vegas, NV 89146 Telephone: 702-871-9888 Facsimile: 702-648-0888 Email: ml@linlawgroup.com

www.linlawlv.com www.linlawgroup.com

Please see if we have fully met all the document requirements for H00-06/09/23. If still missing something, Please feel free to contact me any time.

David He Representative for PBI/UMI TEL 909-682-9518

EMAIL davidmeditech@gmail.com

Prado, Joe < <u>iprado@fresnocountyca.gov</u>> 于 2023年6月9日周五 20:47写道:

David,

I'm attaching a further amended Health Officer Order dated 6-9-23.

To date, PBI/UMI have failed to provide an adequate response to the Health Officer Order. We direct you to the Health Officer Order and the need to comply with all of this Order's requirements by June 11, 2023. The presence of infectious agents at the 850 I Street warehouse is beyond dispute. Additionally please provide updated addresses and phone numbers of Xiaoxiao Wang and Xiuqin Yao.

From: He David < davidmeditech@gmail.com >

Sent: Friday, June 09, 2023 12:45 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理

<jituanguanli@126.com>; info.1320pbi@gmail.com>; Luchini, David
<dluchini@fresnocountyca.gov>; Vohra, Rais <ra>rvohra@fresnocountyca.gov>; Mendes,

Vincent < <u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba

< Nicole. Zieba@reedley.ca.gov >; Dhillon, Simranjit < sidhillon@fresnocountyca.gov >

Subject: Re: 回复: Second Fresno County Health Officer Order

Dear Joe Prado

Your email of yesterday evening has been received. Thank you very much for giving us an extension to June 11.

After receiving your email, I immediately forwarded it to Dimension manager in charge. We had a telephone discussion this morning. He had been calling you several times, but couldn't get through. We are particularly concerned about now is what documents need to be supplemented. You'd better give us a detailed explanation.

The important is whether your department can accept Dimension as the General Contractor for transportation and clearance and destruction of this project. If you agree, please give us a written reply ASAP, so we can plan all the details we need to work together for the further operation. If you think this company is not good enough, then we need to looking for another company quickly, so we need more time to extend.

More importantly, you mentioned in the email that Finding and Evidence of infectious agents in the email on April 7. I did not receive this email, and I also consulted the relevant people, but no one receive such email either. They said the email received on April 7 was sent by Ms.Harper, which only gave explanation and four attachments for guidance of State Regulation and Transportation Reference. Therefore, you still haven't give the solid evidence about the infectious agents. If you have more information, please send to me immediately. We pay special attention to this, which is also closely related to the detailed further operation of the items in the 850 temporary warehouse.

After I told the former staff about the infectious agents in your email, all of them are very surprise. There must be a huge misunderstanding because the infectious agents you mentioned have never been exposed in UMI research and production except recombinant E. coli, which is commonly used in most biological laboratories, and it will certainly not

have any impact on public health. I did not see any similar infectious agents in the list of all items and refrigerator contents provided by UMI. Please provide all the information you have today, so we can continue to hard work over the weekend and reply to you on Monday to meet your order deadline of June 11.

Thank you very much for your special attention.

David He

Representative for PBI/UMI

TEL 909-682-9518

EMAIL davidmeditech@gmail.com

Prado, Joe < iprado@fresnocountyca.gov > 于 2023年6月8日周四 19:37写道:

To All Representatives,

I'm attaching a Revised Health Officer Order that has provided additional time, till June 11, 2023 to complete providing the missing documentation requested in the Health Officer Order dated 5-31-2023 and Revised Order dated 6-8-2023.

Your email dated June 7, 2023 requested our findings related to infectious agents. The items listed below is only an example of the infectious agents found onsite and is not a complete exhaustive list:

Chlamydia trachomatis

E. coli (recombinant strains)

Helicobacter pylori

Mycoplasma pneumoniae and general Mycoplasma species

Neisseria meningitidis

Nostoc species

Sphingobacterium heparinum

Streptococcus pneumoniae Streptococcus species

Toxoplasma gondii

Hepatitis B virus

Hepatitis C virus

Dengue virus

Human Immunodeficiency Virus 1 and 2

Human Herpes virus 1

Human Herpes virus 5

Respiratory Syncytial virus

Rubella virus

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (RG3)

The infectious agents fall under the packaging and shipping requirements included in correspondence provided on April 7, 2023.

Please provide the remaining documentation by June 11, 2023.

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Wednesday, June 07, 2023 2:53 PM **To:** Prado, Joe < iprado@fresnocountyca.gov>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理

<<u>iituanguanli@126.com</u>>; info.1320pbi
<<u>iinfo.1320pbi@gmail.com</u>>; Luchini, David

<<u>dluchini@fresnocountyca.gov</u>>; Vohra, Rais <<u>rvohra@fresnocountyca.gov</u>>;

Mendes, Vincent < <u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba

< Nicole. Zieba@reedlev.ca.gov >; Dhillon, Simranjit < sidhillon@fresnocountyca.gov >

Subject: 回复: Second Fresno County Health Officer Order

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We will prepare the official document of the board resolution as soon as we receive your reply email on Monday. I have now received the documents from two companies.

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If there is anything else I can help, please feel free to contact me.

Sincerely yours

David He
Representative for PBI/UMI
TEL 909-682-9518
EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- 回复的原邮件 ----

发件人 <u>Prado, Joe<iprado@fresnocountyca.gov></u>

日期 2023年06月05日 16:28

收件人 <u>davidmeditech@gmail.com</u> <u>ml<ml@linlawgroup.com></u> <u>clin<clin@linlawgroup.com></u>

集团管理<iituanguanli@126.com> prestibio2021@gmail.com info.1320pbi<info.13

20pbi@gmail.com>

抄送至 <u>Luchini, David<dluchini@fresnocountyca.gov></u> <u>Vohra, Rais<rvohra@fresnocountyca.g</u>

ov> Mendes, Vincent<vmendes@fresnocountyca.gov> Nicole.Zieba<Nicole.Zieba@re

edley.ca.gov> Dhillon, Simranjit<sidhillon@fresnocountyca.gov>

主题 RE: Second Fresno County Health Officer Order

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 - iv. In addition, Section 2.A. was not complied with thus this plan even if complete cannot be accepted.
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 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor.

- 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor.
- c. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.
 - ii. In addition, Section 2.A. was not complied with thus even a signed agreement or purchase order would not comply with our request.

In accordance with the HOO, representatives have seven (7) days from receipt of HOO to provide the necessary documentation. The representatives have until June 7, 2023 to provide the County of Fresno additional documentation that meet the requirements set forth in HOO. The items noted above are based on documentation included in Email. If additional documentation is submitted for consideration please continue to do so as stated in HOO.

Thank you

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Saturday, June 03, 2023 11:30 PM **To:** Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: 集团管理 < iituanguanli@126.com >; ml < ml@linlawgroup.com >; clin

<<u>clin@linlawgroup.com</u>>; Luchini, David <<u>dluchini@fresnocountyca.gov</u>>; Vohra,

Rais < rvohra@fresnocountyca.gov >; Mendes, Vincent

<<u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba <<u>Nicole.Zieba@reedlev.ca.gov</u>>;

Dhillon, Simranjit < sidhillon@fresnocountyca.gov >

Subject: Re: Second Fresno County Health Officer Order

CAUTION!!! - EXTERNAL EMAIL - THINK BEFORE YOU CLICK

Dear Joe Prado

I am David He. As a special representative, I am authorized to manage and deal with the related work of 850 temporary warehouse. Attachment 1 are the authorization documents for your reference.

In the previous period, I had good communication and cooperation with officials at all levels of the federal government, state government and municipal government, and has achieved phased results. After receiving your email and attachment order this Wednesday, we take it very seriously. After three days preparation, I give you a brief report on our previous and current work as following:

As for the disposal plan of 850 items, I sent a detail plan to the local municipal officer 10 days ago. Now I send you the plan officially again with updated information.

1. Background

Clean up and transfer of the goods in the 850 temporary warehouse as soon as possible to completely eliminate potential risks for fire and safety hazards. The finished diagnostic kits that have been identified will be destroyed.

Government officials recommended good handling and destruction professional companies (Dimension Waste Services) . Full service can be carried out according to the plan we have formulated, including warehouse clean up , fully licensed transportation and movement and destruction services.

The brand new Factory with 18,000 square feet building, located in 3900 N Blattella Ln. Fresno CA 93724, will be powered on around June 10th. The final city inspection will be completed within one or two week after that, and the occupancy permit will be issued. However, the final approval is subject to PBI obtain the license of biohazard. The lease contract are doing the final review.

- 2. Transfer all the refrigerators and freezers with the contents to the new site. Remove temporary electricity and water to completely eliminate the risk of fire and flood by listened electrician. This work will be completed around June 19-20.
- 3. Transfer potentially dangerous chemical reagents and solutions to the new site. Completely eliminate potential safety hazards for 850. This work will be completed around June 20-23.
- 4. PBI do the best to apply for the CDPH Medical Waste Registration License according to the regulation of the state government. Formal application documents and cheques have been sent by express mail on this Tuesday. A scanned copy of the full set of document in Attachment 2. We hope this license will be approved next week
- 5. If necessary, the isolation area in the new factory can be set up and the chemical and biological reagents with potential safety risks transported by 850 can be temporarily isolated and blocked by your department officer and waiting for further component confirmation or harmless inspection results.
- 6. Clean up and move general items and equipment. Those with value in use are moved to a new site, and those with no value in use are put into recycling trailers for recycling. This work will be completed around June 26-30th.
- 7. Disposal of embargoed finished products. Since most of the embargoed finished products are placed at the end of the temporary warehouse, it is necessary to wait until all the items are cleared and moved out before they can be shipped out for destruction. When all of these embargoed items are ready to be shipped, choose a suitable day to move out under the supervision of California government officials. This will be completed Early July.
- 8. I received a quote from Dimension company yesterday. Please see the quotation in Attachment 3 and 4 from this company. For this quotation, we have been discussing it over and over again this week with Ben, the manager in charge for this project. We have great confidence the Dimension company. They have full listens for the transportation, handling and destruction of chemical, biological and medical materials. We'd like to start the cooperation as soon as the price is confirmed.

Please give further advice after reviewing the above plan and arrangement. If you have any questions, please feel free to contact me. If possible, I would like to visit you at your office in afternoon of June 9. In this way, we can have a more in-depth discussion on many detailed technical issues and get your guidance. At the same time, I can submit a set of important documents regarding UMI chemical and biological reagents secure coding and labeling, so that you can have a more comprehensive and in-depth understanding of the biochemical and medical reagents stored in the refrigerator.

Best regard and have a nice weekend.

David He Representative for PBI/UMI TEL 909-682-9518 EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- Replied Message ----

From Prado, Joe<jprado@fresnocountyca.gov>

Date 05/31/2023 10:54

To <u>davidmeditech@gmail.com</u> <u>jituanguanli@126.com</u> <u>prestibio2021@gmail.com</u> <u>info.1</u>

320pbi@gmail.com ml@linlawgroup.com clin@linlawgroup.com

Cc <u>Luchini, David<dluchini@fresnocountyca.gov> Vohra, Rais<rvohra@fresnocountyca.g</u>

ov> Mendes, Vincent<vmendes@fresnocountyca.gov> Harper, Jesalyn<Jesalyn.Harper@reedlev.ca.gov> Nicole Zieba, Reedlev<Nicole.Zieba@reedlev.ca.gov> Dhillon, Si

mranjit<sidhillon@fresnocountyca.gov>

Subject Second Fresno County Health Officer Order

Good Morning Representatives,

I am delivering to you Fresno County's Health Officer Order. This second order requires action on your part within 7 days. Please submit all requested documentation to dph@fresnocountyca.gov within 7 days for County's review and consideration. There is a Notice of Rights included in the Order if you have further inquiries. Thank you

Joe Prado, Assistant Director

Department of Public Health Tel: (559) 600-6402 jprado@fresnocountyca.gov

This Email message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact the sender without using reply Email and destroy all copies of the original message.

From: Prado, Joe
To: He David

Cc: ml; clin; 集团管理; info.1320pbi; Luchini, David; Vohra, Rais; Mendes, Vincent; Nicole.Zieba; Dhillon, Simranjit;

prestibio2021

Subject: RE: 回复: Second Fresno County Health Officer Order

Date: Tuesday, June 13, 2023 5:29:54 PM

Dear David,

The Fresno County Department of Health sent you a revised Health Officer Order on Friday June 9, 2023 which extended your response time per your own request. In that order it made it clear that you, as the representative for Universal Meditech Inc. and Prestige Biotech Inc. were to send us information that complied with the order. To date, neither 2A nor 2B have been completed and the time to respond to the Health Order has lapsed.

Regarding 2A, no viable California address has been provided, which violates California Corporations Code Section 1700. Per that section, a California address must be provided that is a street address and has someone available at that address . First you responded with the addresses of empty offices, and when we asked for clarification you provided addresses in China that do not appear to correlate with any maps of the area. The Department is trying to work with you but it is increasingly difficult when it appears that you are not wanting to provide real information. This viable address and phone number requirement pertains to both Universal Meditech Inc., a California corporation, and Prestige Biotech Inc., a Nevada corporation doing business in California.

Regarding 2B, it is the obligation of Universal Meditech Inc. and or Prestige Biotech Inc. to respond to the Health Order, not their contractors. The company or companies that own the materials located at 850 "I" Street, Reedley, CA 93654 are the entities obligated to respond to the Fresno County Department of Public Health's requests. You requested additional time to respond and we provided that time. We told you exactly what parts of the health order were not yet met and still neither company that you represent has addressed those missing portions.

As stated above, the time to respond to the health officer order has lapsed. The Department is now assessing how to abate the matter since it appears that neither Universal Meditech Inc. or Prestige Biotech Inc. have an interest in working with the Department in addressing the biologicals located at 850 "I" Street in Reedley, CA.

I would like to also to let you know we have been in contact with California Department of Public Health – Food & Drug Branch (CDPH-FDB) and you have indicated you are willing to accept the responsibility and manage the destruction of unlicensed medical devices from the warehouse at 850 I street. The contractors for Universal Meditech Inc. and or Prestige Biotech Inc. may enter the site to only remove the medical devices. Please work with City of Reedley and CDPH-FDB to work out the logistics for destruction of medical devices. To ensure clarity, this action does not fulfill the requirements of the Health Officer Order.

From: He David <davidmeditech@gmail.com>

Sent: Saturday, June 10, 2023 3:40 PM

To: Prado, Joe <jprado@fresnocountyca.gov>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba <Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>; prestibio2021 cprestibio2021@gmail.com>

Subject: Re: 回复: Second Fresno County Health Officer Order

All right.

Then I'll wait for your further Instruction.

Prado, Joe < <u>iprado@fresnocountyca.gov</u>> 于 2023年6月10日周六 15:11写道:

David,

Health Officer Order Section 2.A. – I am waiting for County Counsel to decide whether or not the additional information submitted today was sufficient.

Health Order Section 2.B. -

- 1. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction and is an assessment only. The plan does not speak to following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.
 - 1. No plan has been submitted packaging and shipping of infectious agents and the protocols that will be followed.
 - 2. The attachment from Dimension speaks more to disposal and assessment. This plan is sufficient for disposal only.
 - iii. Email from David He speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen infectious

agents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements as a sufficient plan for packaging and shipping of infectious agents. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).

- b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor. Initial subcontractor proposed had an expired certificate.
 - 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor. No packaging and shipping certification of infectious agents have been provided or a plan on transporting infectious agents.
- c. Transporters should have binding commitment

i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.

From: He David <<u>davidmeditech@gmail.com</u>>

Sent: Saturday, June 10, 2023 2:28 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理 <jituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David <dluchini@fresnocountyca.gov>; Vohra, Rais <rvohra@fresnocountyca.gov>; Mendes, Vincent <vmendes@fresnocountyca.gov>; Nicole.Zieba@reedley.ca.gov>; Dhillon, Simranjit <sidhillon@fresnocountyca.gov>; prestibio2021 prestibio2021@gmail.com>

Subject: Re: 回复: Second Fresno County Health Officer Order

Hello Joe

Could you clearly indicate what other documents have not been provided? David

Prado, Joe < jprado@fresnocountyca.gov > 于 2023年6月10日周六 13:59写道:

To All Representatives,

The Health Officer has not been complied with. Previous email noted the discrepancies and there are still outstanding documentation.

Sent via the Samsung Galaxy S21+ 5G, an AT&T 5G smartphone Get Outlook for Android

From: He David <<u>davidmeditech@gmail.com</u>>
Sent: Saturday, June 10, 2023 12:52:05 PM
To: Prado, Joe <<u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理

<iituanguanli@126.com>; info.1320pbi <info.1320pbi@gmail.com>; Luchini, David

<<u>dluchini@fresnocountyca.gov</u>>; Vohra, Rais <<u>rvohra@fresnocountyca.gov</u>>; Mendes, Vincent

<wmendes@fresnocountyca.gov>; Nicole.Zieba <<u>Nicole.Zieba@reedley.ca.gov</u>>; Dhillon, Simranjit <<u>sidhillon@fresnocountyca.gov</u>>; prestibio2021 <<u>prestibio2021@gmail.com</u>>

Subject: Re: 回复: Second Fresno County Health Officer Order

Hello Joe

Thank you very much for your reminder. The addresses and telephone numbers of Xiaoxiao Wang and Xiuqin Yao are updated information as following:

Xiuqin Yao

87 Zhuzhou Road, Nancun Town, Qingdao City, Shandong Province, China. Tel: 18661707755

Xiaoxiao Wang

404 Wanggezhuang Street, Laoshan District, Qingdao City, Shandong Province, China Tel: 13255326066

The official registered address of the company has been listed in the Letter of Board Resolution from both company.

Universal Meditech has formally hired a representative lawyer this year, and the contact information is as follows:

Michael M. Lin, D.C., Esq.

Lin Law Group, P.C.

5288 Spring Mtn. Rd.

Suite 103

Las Vegas, NV 89146 Telephone: 702-871-9888 Facsimile: 702-648-0888 Email: ml@linlawgroup.com

www.linlawlv.com www.linlawgroup.com

Please see if we have fully met all the document requirements for H00-06/09/23. If still missing something, Please feel free to contact me any time.

David He Representative for PBI/UMI TEL 909-682-9518 EMAIL davidmeditech@gmail.com

Prado, Joe < <u>iprado@fresnocountyca.gov</u>> 于 2023年6月9日周五 20:47写道:

David,

I'm attaching a further amended Health Officer Order dated 6-9-23.

To date, PBI/UMI have failed to provide an adequate response to the Health Officer Order. We direct you to the Health Officer Order and the need to comply with all of this Order's requirements by June 11, 2023. The presence of infectious agents at the 850 I Street warehouse is beyond dispute. Additionally please provide updated addresses and phone numbers of Xiaoxiao Wang and Xiuqin Yao.

From: He David <<u>davidmeditech@gmail.com</u>>

Sent: Friday, June 09, 2023 12:45 PM

To: Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理

<i ituanguanli@126.com>; info.1320pbi</br><ii sinfo.1320pbi@gmail.com>; Luchini, David

<<u>dluchini@fresnocountyca.gov</u>>; Vohra, Rais <<u>rvohra@fresnocountyca.gov</u>>;

Mendes, Vincent < <u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba

< Nicole. Zieba@reedley.ca.gov >; Dhillon, Simranjit < sidhillon@fresnocountyca.gov >

Subject: Re: 回复: Second Fresno County Health Officer Order

Dear Joe Prado

Your email of yesterday evening has been received. Thank you very much for giving us an extension to June 11.

After receiving your email, I immediately forwarded it to Dimension manager in charge. We had a telephone discussion this morning. He had been calling you several times, but couldn't get through. We are particularly concerned about now is what

documents need to be supplemented. You'd better give us a detailed explanation.

The important is whether your department can accept Dimension as the General Contractor for transportation and clearance and destruction of this project. If you agree, please give us a written reply ASAP, so we can plan all the details we need to work together for the further operation. If you think this company is not good enough, then we need to looking for another company quickly, so we need more time to extend.

More importantly, you mentioned in the email that Finding and Evidence of infectious agents in the email on April 7. I did not receive this email, and I also consulted the relevant people, but no one receive such email either. They said the email received on April 7 was sent by Ms.Harper, which only gave explanation and four attachments for guidance of State Regulation and Transportation Reference. Therefore, you still haven't give the solid evidence about the infectious agents. If you have more information, please send to me immediately. We pay special attention to this, which is also closely related to the detailed further operation of the items in the 850 temporary warehouse.

After I told the former staff about the infectious agents in your email, all of them are very surprise. There must be a huge misunderstanding because the infectious agents you mentioned have never been exposed in UMI research and production except recombinant E. coli, which is commonly used in most biological laboratories, and it will certainly not have any impact on public health. I did not see any similar infectious agents in the list of all items and refrigerator contents provided by UMI. Please provide all the information you have today, so we can continue to hard work over the weekend and reply to you on Monday to meet your order deadline of June 11.

Thank you very much for your special attention.

David He

Representative for PBI/UMI

TEL 909-682-9518

EMAIL davidmeditech@gmail.com

Prado, Joe < iprado@fresnocountyca.gov> 于 2023年6月8日周四 19:37写道:

To All Representatives,

I'm attaching a Revised Health Officer Order that has provided additional time, till June 11, 2023 to complete providing the missing documentation requested in the Health Officer Order dated 5-31-2023 and Revised Order dated 6-8-2023.

Your email dated June 7, 2023 requested our findings related to infectious agents. The items listed below is only an example of the infectious agents found onsite and is not a complete exhaustive list:

Chlamydia trachomatis

E. coli (recombinant strains)

Helicobacter pylori

Mycoplasma pneumoniae and general Mycoplasma species

Neisseria meningitidis

Nostoc species

Sphingobacterium heparinum

Streptococcus pneumoniae Streptococcus species

Toxoplasma gondii

Hepatitis B virus

Hepatitis C virus

Dengue virus

Human Immunodeficiency Virus 1 and 2

Human Herpes virus 1

Human Herpes virus 5

Respiratory Syncytial virus

Rubella virus

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (RG3)

The infectious agents fall under the packaging and shipping requirements included in

correspondence provided on April 7, 2023.

Please provide the remaining documentation by June 11, 2023.

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Wednesday, June 07, 2023 2:53 PM **To:** Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: ml <ml@linlawgroup.com>; clin <clin@linlawgroup.com>; 集团管理

<<u>iituanguanli@126.com</u>>; info.1320pbi
<<u>iinfo.1320pbi@gmail.com</u>>; Luchini, David

<<u>dluchini@fresnocountyca.gov</u>>; Vohra, Rais <<u>rvohra@fresnocountyca.gov</u>>;

Mendes, Vincent < <u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba

< Nicole. Zieba@reedley.ca.gov >; Dhillon, Simranjit

<sidhillon@fresnocountyca.gov>

Subject: 回复: Second Fresno County Health Officer Order

Dear Joe Predo

We will prepare the official document of the board resolution as soon as we receive your reply email on Monday. I have now received the documents from two companies. Please see the attachments.

At the same time, I have repeatedly communicated with the responsible manager of Dimension company. They have been working hard these two days to meet the requirements you put forward in the mail. They said they would email the file to me and maybe call you later this afternoon. They said that the time you gave was really too short because there are many factors involved in this project and there are different subcontracts involvedand. It would be better to give an extension of two or three days.

Another very important key point is that 230531-HOO clearly mentioned the existence of Infectious Agents in the 850 temporary warehouse. We take this very seriously. Please give us the relevant findings and evidence as soon as possible. Because in the list of items and information we have, we have not get any infectious agents harmful to public health. We would be very grateful if you could pay special attention to this point.

If there is anything else I can help, please feel free to contact me.

Sincerely yours

David He

Representative for PBI/UMI

TEL 909-682-9518 EMAIL davidmeditech@gmail.com



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- 回复的原邮件 ----

发件人 Prado, Joe<iprado@fresnocountyca.gov>

日期 2023年06月05日 16:28

收件人 <u>davidmeditech@gmail.com</u> <u>ml<ml@linlawgroup.com></u> <u>clin<clin@linlawgroup.com</u>

≥ 集团管理<jituanguanli@126.com> prestibio2021@gmail.com info.1320pbi<inf

o.1320pbi@gmail.com>

抄送至 <u>Luchini, David<dluchini@fresnocountyca.gov></u> <u>Vohra, Rais<rvohra@fresnocountyc</u>

a.gov> Mendes, Vincent<vmendes@fresnocountyca.gov> Nicole.Zieba<Nicole.Zie

<u>ba@reedley.ca.gov></u> <u>Dhillon, Simranjit<sidhillon@fresnocountyca.gov></u>

主题 RE: Second Fresno County Health Officer Order

To All Representatives,

We have received and reviewed your response. The response is insufficient and does not meet the requirements set forth in the Health Officer Order dated 5-31-2023 (HOO). Thus actions will continue as stated in the HOO (attached). Here are the deficiencies in the email response from davidmeditech@gmail.com dated June 3rd, 2023 at 11:30pm (Email):

- 1. HOO Section 2.A. has not been complied to due to a Board resolution not being attached. Email attachment contained email statements only not a Board resolution. In addition Section 2.A. requested authorized individuals to conduct business in CA and persons that assume financial responsibilities. No documents presented addressed request in Section 2.A.
- 2. Section 2.B. requires
 - a. Biological abatement, disposal plan, or transport of properly labeled and identified biological agents
 - i. Email attachment labeled EPSON149 is the Medical Waste application plan for the proposed new City of Fresno address. Not applicable to our request.
 - ii. Email attachment labeled Dimension Service Order Prestige Bio (Assessment) speaks to destruction

and is an assessment only. The plan does not speak to following the appropriate packaging and shipping requirements for transporting infectious agents for transport to City of Fresno address. Scope of Work should be inclusive of both medical waste and transport of biological infectious agents. It appears the scope of work omits the transport of infectious agents to the City of Fresno address.

- iii. Email number (2.), speaks to transferring refrigerators and freezers with the contents to new site. This statement demonstrates intention to move refrigerated and frozen contents to a new site which cannot be done by just moving contents with refrigerators/freezers inside of them. This method is not consistent with Packaging and Shipping requirements of infectious agents. Thus this does not meet requirements. Applicable federal and state regulations were provided to representatives on April 7, 2023 (email attached).
- iv. In addition, Section 2.A. was not complied with thus this plan even if complete cannot be accepted.
- b. Transporters have appropriate certification
 - i. The Department is confirming whether Dimension is utilizing a subcontractor to meet federal and State regulations and identify the subcontractor to confirm appropriate certification.
 - 1. Dimension does not have appropriate certification for transporting medical waste but may use a subcontractor.
 - 2. Dimension does not have appropriate certification for packaging and shipping of infectious agents but may use a subcontractor.
- c. Transporters should have binding commitment
 - i. Email had attached quote but no binding commitment was provided. Binding commitment may be a purchase order or agreement with the vendor.
 - ii. In addition, Section 2.A. was not complied with thus even a signed agreement or purchase order would not comply with our request.

In accordance with the HOO, representatives have seven (7) days from receipt of HOO to provide the necessary documentation. The representatives have until June 7, 2023 to provide the County of Fresno additional documentation that meet the requirements set forth in HOO. The items noted above are based on documentation included in Email. If additional documentation is submitted for consideration please

continue to do so as stated in HOO.

Thank you

From: davidmeditech@gmail.com <davidmeditech@gmail.com>

Sent: Saturday, June 03, 2023 11:30 PM **To:** Prado, Joe < <u>iprado@fresnocountyca.gov</u>>

Cc: 集团管理 < iituanguanli@126.com >; ml < ml@linlawgroup.com >; clin

<<u>clin@linlawgroup.com</u>>; Luchini, David <<u>dluchini@fresnocountyca.gov</u>>; Vohra,

Rais < rvohra@fresnocountyca.gov>; Mendes, Vincent

<<u>vmendes@fresnocountyca.gov</u>>; Nicole.Zieba <<u>Nicole.Zieba@reedley.ca.gov</u>>;

Dhillon, Simranjit < sidhillon@fresnocountyca.gov > Subject: Re: Second Fresno County Health Officer Order

CAUTION!!! - EXTERNAL EMAIL - THINK BEFORE YOU CLICK

Dear Joe Prado

I am David He. As a special representative, I am authorized to manage and deal with the related work of 850 temporary warehouse. Attachment 1 are the authorization documents for your reference.

In the previous period, I had good communication and cooperation with officials at all levels of the federal government, state government and municipal government, and has achieved phased results. After receiving your email and attachment order this Wednesday, we take it very seriously. After three days preparation, I give you a brief report on our previous and current work as following:

As for the disposal plan of 850 items, I sent a detail plan to the local municipal officer 10 days ago. Now I send you the plan officially again with updated information.

1. Background

Clean up and transfer of the goods in the 850 temporary warehouse as soon as possible to completely eliminate potential risks for fire and safety hazards. The finished diagnostic kits that have been identified will be destroyed.

Government officials recommended good handling and destruction professional companies (Dimension Waste Services) . Full service can be carried out according to the plan we have formulated, including warehouse clean up , fully licensed transportation and movement and destruction services.

The brand new Factory with 18,000 square feet building, located in 3900 N Blattella Ln. Fresno CA 93724, will be powered on around June 10th. The final city inspection will be completed within one or two week after that, and the occupancy

permit will be issued. However, the final approval is subject to PBI obtain the license of biohazard. The lease contract are doing the final review.

- 2. Transfer all the refrigerators and freezers with the contents to the new site. Remove temporary electricity and water to completely eliminate the risk of fire and flood by listened electrician. This work will be completed around June 19-20.
- 3. Transfer potentially dangerous chemical reagents and solutions to the new site. Completely eliminate potential safety hazards for 850. This work will be completed around June 20-23.
- 4. PBI do the best to apply for the CDPH Medical Waste Registration License according to the regulation of the state government. Formal application documents and cheques have been sent by express mail on this Tuesday. A scanned copy of the full set of document in Attachment 2. We hope this license will be approved next week
- 5. If necessary, the isolation area in the new factory can be set up and the chemical and biological reagents with potential safety risks transported by 850 can be temporarily isolated and blocked by your department officer and waiting for further component confirmation or harmless inspection results.
- 6. Clean up and move general items and equipment. Those with value in use are moved to a new site, and those with no value in use are put into recycling trailers for recycling. This work will be completed around June 26-30th.
- 7. Disposal of embargoed finished products. Since most of the embargoed finished products are placed at the end of the temporary warehouse, it is necessary to wait until all the items are cleared and moved out before they can be shipped out for destruction. When all of these embargoed items are ready to be shipped, choose a suitable day to move out under the supervision of California government officials. This will be completed Early July.
- 8. I received a quote from Dimension company yesterday. Please see the quotation in Attachment 3 and 4 from this company. For this quotation, we have been discussing it over and over again this week with Ben, the manager in charge for this project. We have great confidence the Dimension company. They have full listens for the transportation, handling and destruction of chemical, biological and medical materials. We'd like to start the cooperation as soon as the price is confirmed.

Please give further advice after reviewing the above plan and arrangement. If you have any questions, please feel free to contact me. If possible, I would like to visit you at your office in afternoon of June 9. In this way, we can have a more in-depth discussion on many detailed technical issues and get your guidance. At the same time, I can submit a set of important documents regarding UMI chemical and biological reagents secure coding and labeling, so that you can have a more comprehensive and in-depth understanding of the biochemical and medical reagents stored in the refrigerator.

Best regard and have a nice weekend.

David He Representative for PBI/UMI TEL 909-682-9518 EMAIL <u>davidmeditech@gmail.com</u>



davidmeditech@gmail.com

邮箱: <u>davidmeditech@gmail.com</u>

---- Replied Message ----

From Prado, Joe<jprado@fresnocountyca.gov>

Date 05/31/2023 10:54

To <u>davidmeditech@gmail.com</u> <u>jituanguanli@126.com</u> <u>prestibio2021@gmail.com</u> <u>info</u>

.1320pbi@gmail.com ml@linlawgroup.com clin@linlawgroup.com

Cc Luchini, David<dluchini@fresnocountyca.gov> Vohra, Rais<rvohra@fresnocountyc

<u>a.gov> Mendes, Vincent<vmendes@fresnocountyca.gov> Harper, Jesalyn<Jesalyn.</u> Harper@reedlev.ca.gov> Nicole Zieba, Reedlev<Nicole.Zieba@reedlev.ca.gov> Dh

illon, Simranjit<sidhillon@fresnocountyca.gov>

Subject Second Fresno County Health Officer Order

Good Morning Representatives,

I am delivering to you Fresno County's Health Officer Order. This second order requires action on your part within 7 days. Please submit all requested documentation to dph@fresnocountyca.gov within 7 days for County's review and consideration. There is a Notice of Rights included in the Order if you have further inquiries. Thank you

Joe Prado, Assistant Director

Department of Public Health Tel: (559) 600-6402 jprado@fresnocountyca.gov

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