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January 3, 2022

VIA E-MAIL (ORAPharm1_responses@fda.hhs.gov)
Diana Amador Toro, District Director
Food and Drug Administration, New Jersey Office
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Re: Waiver of Ideal Specialty Apothecary for Publication of Response to FDA Form 483 Issued November 18, 2021

Dear Director Toro:

On behalf of Ideal Specialty Apothecary, I hereby authorize the United States Food and Drug Administration ("FDA") to publicly disclose the information described below on FDA's website. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331 (y)(2), and 5 U.S.C 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Ideal Specialty Apothecary's Response to the FDA Form 483 issued November 18, 2021. The waiver shall extend only to Ideal Specialty Apothecary's Response to the FDA Form 483 Issued November 18, 2021 and not to any of the supporting or underlying documents implicated or involved in the FDA Form 483 issued November 18, 2021 or Ideal Specialty Apothecary's response thereto.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Ideal Specialty Apothecary, and my full name, title, telephone number, and facsimile number is set out above for verification.

In the event there are any questions regarding the disclosure of such information, I hereby request pre-disclosure notification so that we can address any such questions prior to disclosure of the material.

In the interim, please do not hesitate to contact me should you have any questions.

Very truly yours,

SATISH V. POONDI

SVP/js

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November 23, 2021

VIA E-MAIL (ORAPharm1_responses@fda.hhs.gov)
Diana Amador Toro, District Director
Food and Drug Administration, New Jersey Office
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Re: Ideal Specialty Apothecary, Inc.; FEI No.: 3013505558
Response to 483

Dear Director Amador Toro:

Please be advised that I represent the above referenced pharmacy. Please accept this submission in response to the 483 issued to Ideal Specialty Apothecary, Inc. ("Ideal Pharmacy"), located at 2333 Morris Avenue, Ste. B101, Union, New Jersey 07083. A copy of the form FDA 483 is attached, as Exhibit A.

The dates of inspection were September 13, 2021, September 15, 2021, September 17, 2021, September 21, 2021, September 24, 2021, September 28, 2021, September 29, 2021, October 4, 2021, October 12, 2021, October 18, 2021, November 2, 2021, and November 18, 2021. During the inspection, Ideal Pharmacy engaged cooperatively and constructively with FDA. We would like to assure FDA that Ideal Pharmacy is committed to providing patients with the highest quality compounded medications prepared in compliance with all applicable standards and that, as demonstrated herein, the pharmacy takes its professional responsibilities very seriously.

For the reasons set forth below, the pharmacy respectfully disputes portions of the FDA's factual and/or legal findings.

Please note that Ideal Pharmacy makes this submission without conceding the relevancy, materiality, existence, or admissibility of any document or document request, and without prejudice as to its rights to further contest the FDA's findings. In producing or making available for inspection documents in connection with this action, Ideal Pharmacy reserved, and continues to reserve, all claims of privilege and other such protections and further hereby expressly reserves the right to demand the return of all copies of, and object to the use of, any documents or information subject to a claim of privilege or other such protections that are inadvertently disclosed.

Additionally, insofar as the information contained in the enclosed documents includes protected health information, we request the FDA to maintain the same as confidential documents. The records are being produced pursuant to your representations and the HIPAA exception found at 45 C.F.R. 164.512 (b)(1).

Please also be advised that Ideal Pharmacy reserves the right to supplement this response and/or submit additional information as it pertains to this matter and the 483 that has been issued. This letter does not waive any rights Ideal Pharmacy may assert under applicable law. Furthermore, this submission should not be construed as a waiver of Ideal Pharmacy's rights.

As an initial matter, we also note that the pharmacy fully and voluntarily cooperated with FDA throughout the course of this matter. In addition to responding to multiple requests for documentation, the pharmacy and its staff were also made available for multiple interviews. The pharmacy did not refuse to provide any information.

We also note that the pharmacy on multiple occasions requested, but was not provided, citations to statutes and/or regulations that serve as the basis for each of the observations. Furthermore, as to multiple observations, the investigator conceded that she could not refer to any statute, regulation, or FDA guidance document pertaining to the observation, or which served as the basis for the observation. Failure to provide this basic information substantially hinders the ability of the pharmacy to fully respond to the Form 483.

The Form 483 observations attempt to hold Ideal Pharmacy to cGMP standards with which, as a matter of law, Ideal Pharmacy is not required to comply. See 21 C.F.R. part 210 and 211. Ideal Pharmacy objects to any observation in the Form 483 which inappropriately applies cGMP standards. While Ideal Pharmacy is addressing all of FDA's inspectional findings, its cooperation with FDA should not be construed as Ideal Pharmacy agreeing that it is required to comply with cGMP.

Ideal Pharmacy is not a manufacturer. Ideal Pharmacy is a retail pharmacy licensed by the New Jersey Board of Pharmacy that compounds medications pursuant to patient specific prescriptions. Furthermore, Ideal Pharmacy holds an unrestricted license and is in good standing.

FDA's Observations ignore the fact that this pharmacy - which complies with the requirements set forth in Section 503A - is exempt from cGMP regulations. Pharmacies operating under Section 503A of the FDCA are exempt from cGMP in accordance with the newly enacted Drug Quality and Security Act. Specifically, on November 27, 2013, President Obama signed into law the Drug Quality and Security Act ("DQSA"), Pub. L. No. 113-54. Title I of the DQSA, the Compounding Quality Act, eliminated certain unconstitutional advertising provisions from Section 503A, thus effectively re-enacting those provisions and allowing Section 503A unequivocally to go into effect. The statutory provisions, however,

do not expand FDA's inspection authority or alter in any way applicable standards for compounding pharmacies that comply with FDCA Section 503A.

A critical aspect of Section 503A is the explicit recognition that pharmacies acting in compliance with Section 503A are exempt from certain provisions of the FDCA. In light of this Congressional mandate, FDA must adhere to Section 503A and cannot impose more stringent standards on Ideal Pharmacy, such as the cGMP. Section 503 A provides:

> Sections 501(a)(2)(B), 502(f)(l) and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner…..[1]

FDA's non-binding guidance, published July 2, 2014,[2] is completely consistent with the statute. It reiterates that drugs compounded in compliance with Section 503A will be exempt from certain sections of the FDCA including cGMP requirements (Section 503(a)(2)(B)); labeling with adequate directions for use (Section 502(1)(1)); and new drug requirements (Section 505)). Guidance at 2.

Preparation of this Response to FDA's Observations does not constitute an admission or agreement by this Pharmacy to the alleged deficiencies or conclusions set forth in FDA's Observations. None of the actions that may be taken by this Pharmacy pursuant to its response should be considered an admission that an Observation existed or that additional measures should have been in place at the time of the inspection. Without conceding that any of the Observations are applicable, set forth below are the Pharmacy's Responses to each observation. This Pharmacy respectfully requests that if FDA posts the Form 483 issued to this Pharmacy, then FDA shall post this Response along with it, and also provide this Response when FDA provides the Observations to third parties.

Notwithstanding the questionable application of federal manufacturing regulations to a retail pharmacy, we would like to assure FDA that Ideal Pharmacy is committed to providing patients with the highest quality compounded medications prepared in compliance with all applicable standards and that, as demonstrated herein, the pharmacy takes its professional responsibilities very seriously.

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[1] Section 503A(b) further provides that a drug may be compounded if the pharmacist uses bulk substances that (1) comply with the standards of an applicable United States Pharmacopeia ("USP.,) or National Formulary ("NF") Monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are substances that are components of approved drug products; or (3) if neither of the above, then the drug appears on a shortage list developed by the FDA through regulations.

[2] Final Guidance; Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act; Availability; 79 Fed. Reg. 37742 (July 2. 2014).

To that end, patient safety is Ideal Pharmacy's primary concern, and the pharmacy strives to provide the highest quality preparations and services. Ideal Pharmacy has an impeccable safety record concerning the compounded medications that it prepares according to the applicable standards.

Its quality assurance and standard operating procedures ("SOPs") follow demonstrated pharmacy best practices and are designed to produce high-quality compounded sterile preparations. Ideal Pharmacy's practices are based upon New Jersey Board of Pharmacy requirements and other standards applicable to retail pharmacies so that its patients can continue to access high-quality compounded medications to meet their individual medical needs.

Moreover, in several instances, the Form 483 and FDA's observations are on their face incorrect. There a several material errors of fact and any observations premised on these errors should be withdrawn or amended to reflect the actual facts.

In light of the above, without waiving its right to contest FDA's application of cGMPs, Ideal Pharmacy provides the following responses to the Observations set forth in the 483.

OBSERVATION 1

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.

Response:

We respectfully disagree with the conclusion drawn in this observation. As described in USP General Chapter <797>, the semi-annual certification and re-certifications of cleanrooms and Primary Engineering Controls (PECs) are stipulated per the CETA Certification Guide for Sterile Compounding Facilities CAG-003-2006 / current version, and by inclusion in the document for Primary Engineering Control (PEC) and Secondary Engineering Control (SEC) certifications.

The CETA Certification Guide for Sterile Compounding Facilities CAG-003-2006 / v. 13 is the guidance set forth to meet requirements of USP General Chapter <797>. As stated in the CETA document - Section 13.0 states "Airflow Testing - Unidirectional airflow - (13.2.1) "An airflow smoke pattern test should be performed at every certification to verify that the device is integrated into the facility."

As stipulated in USP General Chapter <797>, "should" means recommended but not required for pharmacy compounding. In review of the CETA document within Section of 13.0 – Currently per CETA guidance CAG-003-2006 there are broad procedures for cleanroom smoke testing standards.

This Pharmacy uses a primary engineering control (PEC) manufactured by Germfree Laboratories, Inc. of Ormond Beach, FL, consistent with prevailing pharmacy practice, and this device is certified semi-annually by a qualified outside vendor according to CETA guidance (CETA - CAG-002-2006) and the provider's recommendations. The device in-use at this Pharmacy is in fact unidirectional and able to maintain this under dynamic operating conditions.

As shown in Exhibit B, the testing was in-fact performed under dynamic operating conditions consistent with prevailing practice. The report clearly states the test was conducted "under dynamic conditions".

OBSERVATION 2

Media fills were not performed that closely simulate aseptic compounding operations incorporating, as appropriate, worst case activities and conditions that provide a challenge to aseptic operations.

Response:

We respectfully disagree with the conclusion drawn in this observation. The FDA is holding the pharmacy to a standard that is inapplicable to a compounding pharmacy under FDCA Section 503A and this pharmacy is not a manufacturer of drug for human use.

The Pharmacy has implemented and follows appropriate written procedures to prevent microbial contamination of drug preparations purporting to be sterile; its procedures are not deficient in any applicable respect. In particular, this Pharmacy's procedures and policies for preventing microbial contamination are adopted from USP General Chapter <797>. Furthermore, media fill were performed in accordance with N.J.A.C. 13:39-11.16.

USP General Chapter <797> requires a media fill test that represents the most challenging or stressful
conditions actually encountered by the personnel being evaluated when they prepare CSPs. The Hardy™ CSP High Complexity Media-Fill Challenge Test Kit (Cat # HVH1) media validation kits used by this Pharmacy do reflect the aseptic manipulations characteristic of the compounding conducted. Conducted at the end of the compounding day, this test represents the most challenging sterile compounding processes employed by the pharmacy. Documentation of completion of this activity is contained in each employee's file.

This Pharmacy will continue to review its process and revise current procedures for process simulation testing, expanding methods of testing operators performing these manipulations. Clarification and clear consideration of worst-case aseptic processing conditions will be included in a review of procedures, as well as include follow up procedures in the event of positive results.

OBSERVATION 3

The ISO-5 classified area is located within a non-classified room (segregated compounding area)

Response:

Although we acknowledge your observation, we disagree with your conclusion. As stated, this Pharmacy is a registered pharmacy practicing under the authority of the New Jersey Board of Pharmacy (BOP), complying with both NJBOP and USP General Chapter <797> guidance for pharmacy compounding.

However, the FDA is holding the pharmacy to a standard that is inapplicable to a compounding pharmacy under FDCA Section 503A and this pharmacy is not a manufacturer of drug for human use. The area where the LFGI is located is a Segregated Compounding Area (SCA). Notably, the FDA guidance document relating to the application of Section 503A is silent as to the use of segregated compounding areas. Furthermore, the investigator conceded that she was unaware of any federal regulation or statute that prohibited the use of a segregated compound area.

Pursuant to N.J.A.C. 13:39-11.8, "A pharmacy may utilize compounding aseptic isolators and compounding aseptic containment isolators not located in a cleanroom to prepare compounded sterile preparations, provided the compounding aseptic isolators and compounding aseptic containment isolators can provide isolation from the room and maintain ISO class 5 air quality during dynamic operating conditions." Furthermore, as per USP General chapter <797>, a Primary Engineering Control (PEC), in this case a LFGI, in an SCA is not required by definition to be in a classified room. A LFGI is not affected by personnel moving though the area as personnel cannot disturb the air flow in the PEC compounding area. Per USP General Chapter <797> - as described within the "Placement of Primary Engineering Controls" section, the pharmacy maintains documentation obtained from the PEC's manufacturer that it does indeed maintain proper ISO classed 5 conditions within the PEC, and that placement within an ISO classed 5 buffer room is not required.

Furthermore, since the drugs being compounded are listed on the NIOSH list of hazardous drugs, by statute they must be compounded in a negative pressure environment to satisfy prevailing NJBOP, and OSHA requirements.

Although not yet required by USP General Chapters <797>, <800> or NJBOP regulations, this Pharmacy has chosen to review its physical plant configuration and move to a configuration of its compounding space to comply with the requirements for "Category Two" compounding sterile preparations (CSPs) as outlined in the updated USP Chapters. This will require surrounding the current laminar flow aseptic containment isolator (LFWB) within an ISO 7 class buffer room.

Although the construction of these new rooms is complete because of the COVID-19 pandemic, the NJBOP has not granted approval for the pharmacy to begin to utilize this new suite.

OBSERVATION 4

The final containers/closures used for drug products intended to be sterile were not maintained to ensure that drug products intended to be sterile maintain sterility.

Response:

We respectfully disagree with your conclusion. Further the process described in the handling of the vials in the pharmacy's compounding process is incorrect. The pharmacy does not assemble the vial-stopper-ferrule assembly and crimp the vials closed in the pharmacy. Ideal utilizes commercially available pre-sterilized glass vials as their final container. These pre-sterilized glass vials are accompanied with a Certificate of Analysis for each lot procured and are handled with care, during storage, compounding, and filling processes consistent with prevailing pharmacy practice and the manufacturer's instructions.

Further, these containers are consistent with the vials used during our initial analytical testing to establish the pharmacy's beyond use dating (BUD), for these preparations consistent with both USP General Chapter <797> and NJBOP regulation. Since the compounding process used during the pharmacy's initial studies is the same as it is today, the single puncture of the vial septum during the filling of the vials in the pharmacy's compounding process has been accounted for, and has been tested to assure both sterility (as verified by USP General Chapter <71> testing) as well as the integrity of the container closure system through the labelled BUD (as verified by the time studies on file in the Pharmacy).

The attachment of a foil-seal to the ferrule of the vial is to assure tamper evidence and not to augment the container closure system. So, the timing of the attachment of that tamper evident seal is immaterial to the discussion of the preparation's overall integrity.

OBSERVATION 5

Non-microbial contamination was observed in your compounding area

Response:

We acknowledge your observation but disagree with your conclusion. Specifically, we object to the terms "corroded" and "appeared to be rust" as there is no evidence to support the use of those terms. Furthermore, FDA is holding the pharmacy to a standard that is inapplicable to a compounding pharmacy under FDCA Section 503A.

The area where the LFGI is located is a Segregated Compounding Area (SCA) not a sterile production area. Per USP General chapter <797>, a Primary Engineering Control (PEC), in this case a LFGI, in a SCA is not required to be in a classified room. However, Ideal Pharmacy will review and further refine the processes for cleaning the interior of the autoclaves, the autoclave trays, and investigate the alleged discoloration on the ceiling. Ideal Pharmacy will replace the blocks holding the autoclaves to a more suitable material, but in doing so we note that the observation is arbitrary and contrary to the advice offered by FDA on prior visits to the pharmacy.

Ideal Pharmacy's independent outside certification provider, Solana & Sons, Inc. of Commack, NY has most recently certified its equipment without comment. The performance testing and viable sampling of the device was conducted consistent with USP General Chapter <797>, Guidance provided by the Controlled Environmental Testing Association (CETA), as referenced with USP General Chapter <797>, and New Jersey Board of Pharmacy regulations.

OBSERVATION 6

Vermin was observed present in areas immediately to your compounding area.

Response:

We acknowledge your observation but disagree with your conclusions. Any insects observed were noted as the flying variety, and as such were most likely introduced into the general pharmacy area from the front door pharmacy entrance.

Upon noticing the presence of the insect, the Pharmacist-in-Charge (PIC) quickly dispatched the insect mechanically, without using any chemicals or insecticides. Additionally Ideal does maintain a qualified and NJ licensed outside pest control service. Per its policy 02-07.01 Pest Control Plan , attached hereto as Exhibit C, that provider utilizes EPA approved humane rodent & insect traps, employees EPA approved agents around the perimeter of the compounding area but does not introduce any agents within the compounding spaces.

If needed, alerted by employee reports of any insect sightings, the contractor would be altered to provide additional services as required. Since the PIC or other staff did not see or report any insects this was not done.

OBSERVATION 7

Your firm compounded drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the compounding environment and product.

Response:

We respectfully disagree with the conclusion drawn in this observation. As an initial matter the area where the construction occurred is approximately 24 feet away from the segregated compounding area. Next, the construction was conducted under the auspices of the New Jersey Board of Pharmacy. Ideal Pharmacy submitted a remodeling application to the New Jersey Board of Pharmacy, pursuant to N.J.A.C. 13:39-4.8. Furthermore, during construction, the pharmacy took appropriate safeguards, including the placement of physical containment barriers between the construction area and the remainder of the pharmacy. We note that the investigator did not request any information relating to the construction and was not physical present during the construction. Accordingly, this observation is based wholly on speculation.

In closing, we respectfully submit this response to explain and distinguish Ideal Pharmacy's operational processes and to clarify what may have been misinterpreted by the FDA field investigator who visited the pharmacy.

Ideal Pharmacy emphasizes that it takes patient safety and its professional responsibilities very seriously. Ideal Pharmacy shares FDA's goal of ensuring that patients in need of custom compounded medications receive quality preparations. To that end, and although it is not required to do so, Ideal Pharmacy has voluntarily taken corrective measures identified herein.

We respectfully submit that these measures more than adequately address FDA's observations, and otherwise should exceed FDA's expectations in this matter. We look forward to discussing this matter with you.

In the interim, please do not hesitate to contact me should you have any questions.

Very truly yours,

SATISH V. POONDI

AJC/cg
Enclosures
cc: Ideal Pharmacy
Helen Verdel, Investigator