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December 4, 2022

VIA E-MAIL (ORAPHARM1_RESPONSES@fda.hhs.gov) & (lisa.harlan@fda.hhs.gov)
Lisa Harlan, Program Division Director
Food and Drug Administration, New Jersey Office
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Re: CareFirst Specialty Pharmacy LLC; FEI No.: 3012258924
Response to 483

Dear Director Harlan:

Please be advised that I represent the above referenced pharmacy. Please accept this submission in response to the 483 issued to CareFirst Specialty Pharmacy LLC ("CareFirst Specialty Pharmacy"), located at 400 Fellowship Road, Ste. 100, Mount Laurel, New Jersey. A copy of the form FDA 483 is attached, as Exhibit A.

The dates of inspection were November 15, 2022 (***beginning at approximately 10:30, and approximately 90 minutes after the pharmacy's operations for the day commenced***), November 16, 2022, November 17, 2022, November 21, 2022, November 23, 2022, and November 30, 2022. During the inspection, CareFirst Specialty Pharmacy engaged cooperatively and constructively with FDA. We would like to assure FDA that CareFirst Specialty Pharmacy is committed to providing patients with the highest quality non-sterile 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 CareFirst Specialty 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, CareFirst Specialty 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 CareFirst Specialty 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 CareFirst Specialty Pharmacy may assert under applicable law. Furthermore, this submission should not be construed as a waiver of CareFirst Specialty 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.

The Form 483 observation attempts to hold CareFirst Specialty Pharmacy to cGMP standards with which, as a matter of law, CareFirst Specialty Pharmacy is not required to comply. See 21 U.S.C. § 353a(a)(1)-(2). CareFirst Specialty Pharmacy objects to the observation in the Form 483 which inappropriately applies cGMP standards. While CareFirst Specialty Pharmacy is addressing all of FDA's inspectional findings, its cooperation with FDA should not be construed as CareFirst Specialty Pharmacy agreeing that it is required to comply with cGMP.

CareFirst Specialty Pharmacy is not a manufacturer. CareFirst Specialty Pharmacy is a retail pharmacy licensed by the New Jersey Board of Pharmacy that compounds non-sterile medications pursuant to patient specific prescriptions for humans and compounds non-sterile medications for veterinary use. Furthermore, CareFirst Specialty Pharmacy holds an unrestricted license which is in good standing.

To this end, we note that the category of establishment FDA lists on the Form 483 - "Producer of Non-Sterile Drug Products" - is not a category recognized in any statute, rule, or guidance. Similarly, FDA also has not published any regulations or even non-binding agency guidance that would provide inspection standards. Congress passed Section 503A, which, along with its exemption from cGMP, applies to this Pharmacy.

FDA's Observation ignores 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 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 CareFirst Specialty 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.

The Form 483 also appears to improperly hold CareFirst Specialty Pharmacy to standards outside applicable State and federal law to determine if its compounds are prepared under insanitary conditions and are therefore adulterated under Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act ("Section 501(a)(2)(A)"). CareFirst Specialty Pharmacy is entitled to Section 503A's exemption from cGMP as a pharmacy acting within its requirements, and therefore FDA should only hold CareFirst Specialty Pharmacy to State law standards when evaluating the conditions under which CareFirst Specialty Pharmacy's compounds are prepared. As such, to the extent it is doing so, FDA cannot use Section 501(a)(2)(A) to apply cGMP or some other standards outside of State law to evaluate CareFirst Specialty Pharmacy.

Preparation of this Response to FDA's observation does not constitute an admission or agreement by this Pharmacy to the alleged deficiency or conclusions set forth in FDA's Observation. 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 is Pharmacy's Response to the single observation. CareFirst Specialty Pharmacy respectfully requests that if FDA posts the Form 483 issued to

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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).

this Pharmacy, then FDA shall post this Response along with it, and also provide this Response when FDA provides the Observation to third parties.

Notwithstanding the inappropriate application of federal manufacturing regulations to a retail pharmacy, we would like to assure FDA that CareFirst Specialty 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.

To that end, patient safety is CareFirst Specialty Pharmacy's primary concern, and the pharmacy strives to provide the highest quality preparations and services. CareFirst Specialty 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 non-sterile preparations. CareFirst Specialty 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, the Form 483 and FDA's observation is on its face incorrect. There is a material error of fact and the observation premised on this error 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, CareFirst Specialty Pharmacy provides the following responses to the Observation set forth in the 483.

OBSERVATION 1

Non-microbial contamination was observed in your production area.

Specifically, unidentified residue buildup was observed during the walkthrough conducted on 11/15/2022 in both corners of the back wall of Bench 101 which was used to produce drug products.

RESPONSE

We acknowledge your observation but disagree with your conclusion, both factually and as a matter of law. As stated, CareFirst Specialty Pharmacy is a registered pharmacy practicing under the authority of the New Jersey Board of Pharmacy (NJBOP), complying with both NJBOP and USP General Chapter <795>- *Pharmaceutical Compounding – Nonsterile Preparations*, guidance for Environmental Quality and Control of our compounding rooms.

FDA's Observation is factually incorrect. The residue identified was created in the normal and routine course of the compounding process and contained within the Controlled Ventilated Enclosure (CVE), commonly referred to as a "powder hood," identified and marked as "Bench 101." Note that Bench 101 is located in CareFirst Specialty Pharmacy's Non-Hazardous Non-Sterile (Non-USP 800) compounding room. The investigators observed compounding activities in multiple benches during their inspection of the compounding room and Bench 101 was observed to contain powder and residue. The powder and any residues were created by the normal daily use of the CVE. The compounds made that day at that particular bench used the same active ingredient from the same lot number.

The walk-through by the FDA inspectors occurred during the compounding day, not at the beginning of the compounding day; the CVE was in-use and not terminally cleaned. Upon the identification of this condition of the CVE, once the compounding was completed for that particular and the CVE was no longer being used for compounding, the trained staff cleaned the CVE pursuant to its policies and procedures and removed any residues of the active pharmaceutical ingredients (API) or other components being prepared within. Attached as Exhibit B are photo(s) of "Bench 101" post-cleaning to demonstrate the usual end-of-day condition of the device.

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

CareFirst Specialty Pharmacy emphasizes that it takes patient safety and its professional responsibilities very seriously. CareFirst Specialty 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, CareFirst Specialty 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

SVP/js
Enclosures
cc: CareFirst Specialty Pharmacy LLC