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October 21, 2015

VIA COURIER

Ms. Diane Amador-Toro
Director
New Jersey District Office
Food and Drug Administration
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Re: Waiver Of Wedgewood Village Pharmacy, Inc. ("Wedgewood Pharmacy") for Publication of Response to FDA Form 483 Issued September 29, 2015

Dear Ms. Amador-Toro:

On behalf of Wedgewood Village Pharmacy, Inc. ("Wedgewood Pharmacy"), 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: Wedgewood Pharmacy's Response to the FDA Form 483 Issued September 29, 2015. The waiver shall extend only to Wedgewood Pharmacy's Response to the FDA Form 483 issued September 29, 2015 and not to any of the supporting or underlying documents implicated or involved in the FDA Form 483 issued September 29, 2015 or Wedgewood Pharmacy'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 Wedgewood Pharmacy, and my

full name, title, address, 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. Thank you.

Very truly yours,

Rachael Pontikes

Rachael G. Pontikes RAL

RGP:ral

October 20, 2015

VIA HAND DELIVERY

Ms. Diane Amador-Toro
Director
New Jersey District Office
Food and Drug Administration
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Re: Response to Inspectional Observations
Issued to Wedgewood Village Pharmacy, Inc.

Dear Ms. Amador-Toro:

Wedgewood Village Pharmacy, Inc. ("Wedgewood Pharmacy") would like to take this opportunity to respond to the inspectional observations listed on the Form 483 dated September 29, 2015 and subsequently reissued on September 30, 2015 ("Form 483"). During FDA's inspection, Wedgewood Pharmacy engaged cooperatively and constructively with FDA. Wedgewood Pharmacy would like to assure FDA that it is committed to providing patients with the highest quality compounded preparations. Wedgewood Pharmacy takes FDA's observations and its professional responsibilities very seriously.

Wedgewood Pharmacy is a New Jersey licensed pharmacy, which compounds and dispenses in compliance with New Jersey law, the applicable laws in other states where Wedgewood Pharmacy is licensed, and USP Chapter 797 and USP Chapter 795, which are the recognized pharmacy standards for sterile and non-sterile compounding. Wedgewood is accredited by the Pharmacy Compounding Accreditation Board ("PCAB"), an independent accreditation board that requires all accredited pharmacies to achieve and maintain compliance with USP 795 and 797. As indicated during FDA's inspection, the majority of the prescriptions that Wedgewood Pharmacy compounds are for use in animals. Regarding drugs compounded for human use, Wedgewood Pharmacy compounds in compliance with Section 503A of the Federal Food, Drug & Cosmetic Act ("Section 503A").

During the inspection, Wedgewood Pharmacy was told that FDA was inspecting to confirm that Wedgewood Pharmacy's practices conformed with the responses to FDA's 2013 inspectional observations. Wedgewood Pharmacy's responses to FDA's 2013 observations demonstrate that the pharmacy is clearly committed to thoroughly and thoughtfully addressing all FDA's observations to ensure patient safety. In response to this Form 483, Wedgewood Pharmacy is again committing to taking action to address each of FDA's observations.

We would like to note, however, that during the inspection and on the Form 483, FDA made no observation indicating that Wedgewood Pharmacy is acting outside the scope of 503A. Section 503A specifically exempts pharmacies from complying with Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act ("FDCA"), which requires compliance with cGMP. 21 U.S.C. 353a(a)(1)-(2). Therefore, Wedgewood Pharmacy is not required to meet the current good manufacturing practices ("cGMP") standards that are required of drug manufacturers.

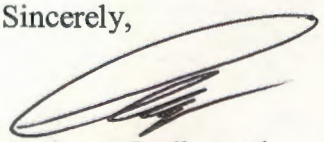
Despite this fact, during the inspection, Wedgewood Pharmacy was informed that it was being inspected against cGMP standards. As a result, all the Form 483 observations hold Wedgewood Pharmacy to cGMP standards, with which, as a matter of law, Wedgewood Pharmacy is not required to comply. See 21 U.S.C. 353a(a)(1)-(2). Wedgewood Pharmacy objects to any observation in the Form 483, which inappropriately applies cGMP standards. While Wedgewood Pharmacy is addressing all FDA's inspectional findings, its cooperation with FDA should not be interpreted as Wedgewood Pharmacy's agreement that it is required to comply with cGMP, thereby leaving Wedgewood Pharmacy exposed to repeat citations for failing to conform with cGMP.

As demonstrated in the following responses, Wedgewood Pharmacy is thoroughly addressing each of the observations presented in the Form 483. In this same vein, Wedgewood Pharmacy is evaluating its overall policies and procedures and will revise them as deemed necessary, to ensure that Wedgewood Pharmacy complies with FDA's expectations, in conjunction with those of New Jersey Board of Pharmacy and the other states' regulatory bodies where Wedgewood Pharmacy holds a pharmacy license.

We appreciate the opportunity to address the observations set forth in the Form 483 and engage in a constructive dialogue regarding Wedgewood Pharmacy's compounding processes. To that end, if FDA has any questions regarding our responses or would like to discuss these responses further, we welcome a meeting with the District Office to continue this dialogue to resolve any outstanding issues regarding the observations noted in the Form 483.

Our specific responses to the observations set forth in Form 483 are attached.

Sincerely,



Anthony Grzib, R.Ph.

AG/attachment

cc: Rachael G. Pontikes, Esq.,
David Rosen, BS Pharm., JD

WEDGEWOOD PHARMACY'S RESPONSES TO FDA'S INSPECTION OBSERVATIONS

FDA Observation 1:

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your previous FDA inspection in February 2013 cited a lack of raw material and finished product testing. Your firm did not fully implement corrective and preventative actions. You continue to formulate your drug products without verifying that you are receiving valid certificates of analysis (C of As). You have not fully qualified your suppliers by periodically having a lot of the Active Pharmaceutical Ingredient (API) analyzed and you are not performing at least one unique identity test to assure that there were no product label mix-ups by the supplier. Your firm only tests a small percentage of your finished product for potency.

In June 2013, your firm recalled veterinary drug products that your firm prepared and labeled as containing Trimeprazine (as Tartrate) 5mg/capsule (e.g., Batch ID 200-20120620 Use By 6/15/13) that did not contain API Trimeprazine Tartrate USP. You only detected the problem with the Trimeprazine Tartrate API because the API manufacturer's C of A included a retest date of July 2013 and you wanted to extend the shelf life for your inventory balance of this lot of API. You had two contract laboratories analyze the API and both confirmed that the API was not Trimeprazine Tartrate USP. One of the laboratories determined that it was actually tartaric acid.

Wedgewood Pharmacy's Response:

Wedgewood Pharmacy respectfully submits that its current process of verifying that it receives valid certificates of analysis (C of As) is compliant with the relevant provisions of Section 503A as well as applicable state regulations. Wedgewood Pharmacy is not aware of any Federal or state law or any FDA guidance that requires a pharmacy compliant with Section 503A to perform laboratory testing of incoming Active Pharmaceutical Ingredients (APIs) to verify that it is receiving valid C of As. Nevertheless, to further address FDA's observation, Wedgewood Pharmacy will engage an outside independent consultant to analyze Wedgewood Pharmacy's current process for qualifying API suppliers to ensure the validity of its API C of As. Wedgewood Pharmacy expects to have reviewed and incorporated any recommendations made by this independent consultant into its current process by first quarter 2016.

As described in Wedgewood Pharmacy's March 2013 response to FDA's February 2013 inspection, Wedgewood Pharmacy's policies have historically required all incoming lots of API to be accompanied by a C of A. Wedgewood Pharmacy's policies have stated that no API is to be used in a compounded preparation until Wedgewood Pharmacy has verified receipt of that API's C of A and required a visual inspection of incoming APIs to confirm that the appearance and physical characteristics of the incoming material match those described on that material's C of A.

In response to FDA's February 2013 inspection, however, Wedgewood Pharmacy instituted an additional process for qualifying API suppliers to verify the validity of a supplier's C of A. This

additional process requires researching suppliers' business, operational, and quality practices, determining suppliers' current registration and inspectional status with FDA, reviewing any FDA regulatory reports of inspections, reviewing any recalls, and performing site audits of suppliers' facilities to ensure acceptable quality assurance. This additional process became operational in June 2013 and continues today. Wedgewood Pharmacy's current process for qualifying API suppliers and verifying the validity of a C of A is consistent with both requirements in Section 503A that it obtain a valid C of A for its APIs and New Jersey Board of Pharmacy requirements.

As to the specific example given in this observation, Wedgewood Pharmacy respectfully notes that this instance occurred prior to the full implementation of Wedgewood Pharmacy's current API supplier qualification process. To provide further insight into this example, Wedgewood Pharmacy utilized a second contract laboratory to conduct identity testing only when the first laboratory did not have the requisite expertise to perform the required testing.

Wedgwood Pharmacy believes that its current policies with its fully implemented API supplier qualification process provide an adequate basis to assess the validity of the supplier's C of A as required by Section 503A. Since it has been fully implemented, the API supplier qualification process has caused Wedgewood Pharmacy to discontinue accepting API from a certain supplier based on an onsite audit who, shortly thereafter, issued a recall for its APIs at FDA's request.

FDA Observation 2:

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your environmental monitoring of cleanroom operations is not generating enough data to be statistically significant to provide assurance that your cleanroom is operating in a continuous state of control. By your estimates your firm's cleanroom is processing approximately 20 batches of drug product a day (from 10 to about 1500 units per batch). For example:

(A) Your environmental monitoring of cleanroom operators is limited to monitoring their gloved hands once every six months. Your procedures also do not require the operator's gowning attire to be monitored. Your operator's arms repeatedly enter the critical ISO-5 area to aseptically manipulate sterile drug products. Their upper bodies periodically lean into the ISO-5 area to clean and sanitize the laminar flow hood and to suspend drug products and components from the overhead hooks.

(B) You only monitor the cleanroom air quality for non-viable particles once every six months, as part of your re-certification program for your laminar flow hoods and the HEPA filters in the ceiling.

(C) You only monitor the cleanroom air quality for viable air particle counts and cleanroom contact surfaces for microbial contamination once a month.

Wedgewood Pharmacy's Response:

Wedgewood Pharmacy respectfully submits that its current processes for monitoring the environmental conditions of its aseptic processing areas meet or exceed New Jersey Board of Pharmacy and USP Chapter 797 standards. FDA's observation seems to apply cGMP standards, with which Wedgewood Pharmacy, as a pharmacy complaint with Section 503A, is not required to comply. However, to address FDA's observation, Wedgewood Pharmacy will engage an outside independent consultant to analyze Wedgewood Pharmacy's current environmental monitoring processes for its cleanroom

operations in order to assess what, if any, changes to monitoring frequency Wedgewood Pharmacy should implement. Wedgewood Pharmacy expects to have reviewed and incorporated any recommendations made by this independent consultant into its current process by first quarter 2016.

To further address Observation 2(A), Wedgewood Pharmacy will also require personnel engaged in aseptic processes within the ISO-5 environment to undergo retraining to ensure that there is minimal encroachment of their upper bodies into the ISO-5 environment. This retraining will be completed and documented on or before November 30, 2015.

FDA Observation 3:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

(A) Your media fills performed to evaluate whether sterile drugs and sterile components can be aseptically processed are not factoring in complex operations or worse-case conditions.

(B) Your smoke studies performed to evaluate whether the design and set-up of your aseptic processing operations create turbulence in the unidirectional HEPA filtered airflow and potentially compromising the sterile drug processing operations were not performed under fully dynamic conditions, which simulate complex aseptic processes.

Wedgewood Pharmacy's Response:

Before describing the actions to be taken to address this observation, Wedgewood Pharmacy would like to provide a more detailed insight into the observation itself.

As to Observation 3(A), each individual engaged in sterile compounding undergoes a media fill verification process every six months as required by New Jersey Board of Pharmacy regulations and USP Chapter 797. This media fill process follows Wedgewood Pharmacy's most complex high risk level sterile compounding operations. This includes starting with non-sterile powdered soy media to produce a non-sterile soy solution, sterilization of that solution via a 0.22 micron sterile filter, followed by aseptic packaging into sterile vials.

As to Observation 3(B), Wedgewood Pharmacy utilizes a qualified outside contractor to perform smoke studies within the ISO-5 environment of each of its laminar airflow hoods. These smoke studies are conducted every six months under dynamic conditions in compliance with both New Jersey Board of Pharmacy requirements and USP Chapter 797 standards.

Nevertheless, Wedgewood Pharmacy will address this observation by implementing the following. To address FDA Observation 3(A) Wedgewood Pharmacy will engage an outside independent consultant to analyze Wedgewood Pharmacy's current media fill process. Any revisions to the media fill process will be implemented by first quarter 2016.

To address FDA Observation 3(B), Wedgewood Pharmacy will consult with an independent consultant and the outside contractor currently performing smoke studies to determine what improvements could

be made to both the execution and documentation of the dynamic smoke studies. Wedgewood Pharmacy expects to have smoke studies incorporating any improvements completed on or before December 31, 2015.

FDA Observation 4:

Clothing of personnel engaged in the processing and packaging of drug products is not appropriate for the duties they perform.

Specifically, your cleanroom gowning procedure potentially compromises the integrity of the sterile gowns used to form a barrier between the cleanroom operators and the ISO 5 critical work area where sterile drug products are aseptically manipulated in HEPA filtered laminar flow hoods. Your operators wash and sanitize their hands but then handle the outside of the sterile gowns (and sleeves) with their bare hands. Then they don a pair of sterilized gloves.

Wedgewood Pharmacy's Response:

Before describing the actions to be taken to address this observation, Wedgewood Pharmacy would like to clarify what was being observed. The clothing of personnel engaged in operations within Wedgewood Pharmacy's cleanrooms is appropriate for duties being performed, as described within the observation– personnel are washing and sanitizing their hands, donning sterile gowns, and donning sterile gloves. FDA's observation is addressing the order in which this garb is being donned, specifically that sterile gowns are being donned prior to sterile gloves. The manner in which Wedgewood Pharmacy's personnel are donning cleanroom garb is exactly what the New Jersey Board of Pharmacy requires. N.J. Admin. Code § 13.39-11.14 (a)-(b) (2013) (requiring personnel enter the clean room, perform antiseptic hand cleansing with a waterless alcohol-based hand scrub, wait for hands to dry, and then don sterile gloves). While donning two sets of sterile gloves – one prior to donning sterile gowns and the second after entering the cleanroom – may appear to satisfy both of the regulators' expectations, the New Jersey Board of Pharmacy requires that the waterless alcohol-based surgical hand scrub be applied to the operator's bare hands in order to ensure persistent antimicrobial activity on the operator's skin. N.J. Admin. Code § 13.39-11.14 (b) (2013).

As such, New Jersey Board of Pharmacy garbing requirements directly conflict with Observation 4, as this observation seems to indicate that FDA expects personnel to don sterile gloves prior to donning sterile gowns. Wedgewood respectfully submits that FDA is not given authority via Section 503A to set out expectations like Observation 4. As a pharmacy operating in compliance with Section 503A, Wedgewood Pharmacy is primarily regulated by the New Jersey Board of Pharmacy, and must look to and comply with all New Jersey Board of Pharmacy regulations regarding the processes surrounding its compounding practices.

Nevertheless, in order to make a good faith effort to comply with both FDA's expectations and the New Jersey Board of Pharmacy requirements, Wedgewood Pharmacy will implement an additional step to its garbing process. Personnel will follow the same hand washing, garbing, and gloving process currently in place in order to comply with New Jersey Board of Pharmacy requirements, but immediately after donning sterile gloves within the ISO 7 cleanroom, Wedgewood Pharmacy personnel will done sterile sleeve covers over the sleeves of the current sterile gown. In this manner, if an operator happens to touch the sleeve of a sterile gown with his or her bare hands during the current

gowning process as described within this observation, sterile sleeve covers handled only with sterile gloved hands will cover any potentially touched areas of the operator's sterile gown. Wedgewood Pharmacy will document this additional step into its cleanroom garbing procedure and expects to have this process implemented on or before December 31, 2015.

FDA Observation 5:

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm failed to fully investigate and document the decisions and corrective actions taken after a storm abruptly shut down power for two days in June 2015. You had work in-process when the power went out, your cleanrooms lost ventilation and their positive pressure gradient, and your refrigerators and freezers warmed to ambient temperature with drug substances, work-in-process materials, and finished drug products inside them.

Wedgewood Pharmacy's Response:

Before describing the actions to be taken to address this observation, Wedgewood would like to provide a more detailed insight into the observation itself. During the June 2015 power outage and in its aftermath, Wedgewood Pharmacy did the following:

- Sterile preparations in-process at the time the power went out were immediately destroyed. The destruction of these preparations was documented in Wedgewood Pharmacy's quality event management system.
- Non-sterile preparations in-process at the time the power went out were immediately destroyed. The destruction of these preparations was documented on the individual batch records of the in-process items.
- No work-in-process materials were being stored in Wedgewood Pharmacy's refrigerators or freezers at the time of the power outage.
- All raw materials and finished preparations that were in the refrigerators and freezers during the power outage were immediately quarantined once power was restored.
- Wedgewood Pharmacy's pharmacists researched and documented stability information on every raw material and finished preparation stored in the refrigerators and freezers at the time of the power outage in order to determine what, if anything, could be retained by Wedgewood Pharmacy in order to prevent any disruptions in patient medication therapy.
- In cases where the item's stability at ambient temperature for 36 hours could not be supported by research, Wedgewood Pharmacy destroyed these items. In cases where scientific information supported the item's ability to remain stable after a 36 hour excursion to ambient temperature, Wedgewood Pharmacy retained this scientific information and placed the items back into active inventory.
- Outside air temperatures during the power outage remained relatively low, so ambient storage area temperatures remained constant, meaning there was no impact on drugs stored at room temperature.
- Once power was restored, Wedgewood Pharmacy conducted a thorough cleaning of its controlled environments, including clean rooms, according to Wedgewood Pharmacy's cleaning procedure. This cleaning was documented in Wedgewood Pharmacy's cleaning logs.

The day after power was restored; FDA's New Jersey District Office contacted Wedgewood Pharmacy asking if the pharmacy had been affected by the storm. In a follow up conversation on June 30, 2015, Wedgewood Pharmacy told FDA about the power outage, and described all of the actions Wedgewood Pharmacy had taken in response, particularly that Wedgewood Pharmacy was in the process of researching and documenting the stability of refrigerated and frozen items. During this exchange, FDA expressed no concerns about Wedgewood Pharmacy's power outage protocol.

However, to address this observation, Wedgewood Pharmacy will evaluate its current processes for evaluating and recording any unexpected or unusual occurrences and will update its SOP to clarify how these events will be documented if they occur. In addition, Wedgewood Pharmacy will review and update its SOP that specifically addresses actions and responsibilities during a power outage. Wedgewood Pharmacy expects these updates to be completed on or before January 31, 2016.

FDA Observation 6:

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.

Specifically, after the previous FDA inspection in 2/2013, your firm initiated a program to assure that your cleaning procedures were effectively removing the drug residue from multi-use equipment prior to using that equipment to process the next drug product. Your protocol (plan) based primarily on drug solubility and total organic carbon (TOC) analysis did not address a number of critical parameters, e.g. the potency of certain drug products if left on equipment in trace amounts, the effectiveness of the swab recovery method and the meaningfulness of the data collected. A final report summarizing whether the plan was effective was not completed or could not be located. A plan was not established for periodic monitoring of cleaning effectiveness.

Wedgewood Pharmacy's Response:

Before describing the actions to be taken to address this observation, Wedgewood Pharmacy would like to provide a more detailed insight into the observation itself. Based upon our discussions with FDA Investigator Glapion, we understand this observation refers only to Wedgewood Pharmacy's protocol for verifying the effectiveness of procedures for cleaning equipment and utensils used in preparing non-sterile finished compounds. Wedgewood Pharmacy employs different cleaning procedures, verified by a separate protocol, for cleaning and sanitizing equipment and glassware used to prepare sterile compounds which is not mentioned in this observation.

To address this observation, Wedgewood Pharmacy is preparing a final report summarizing the data collected during the study referred to in this observation in order to document the effectiveness of the procedures used for cleaning non-sterile equipment and utensils. Wedgewood Pharmacy expects to have this final report completed on or before November 30, 2015. In addition, Wedgewood Pharmacy will update its SOPs to include a monthly audit of its cleaning effectiveness for its non-sterile equipment and utensils. This audit will include visual inspections of cleaned equipment and confirmation that the personnel and equipment used in cleaning processes are operating within established and verified cleaning procedures. Wedgewood Pharmacy expects to have this audit procedure documented and implemented by first quarter 2016.