U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Sunrise Pharmaceutical, Inc. 1/14/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Waterview Corporate Center
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Parsippany, NJ 07054
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January 14, 2010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Utpal Patel
Chief Executive Officer
Sunrise Pharmaceutical, Inc.
665 E. Lincoln Avenue
Rahway, New Jersey 07065

10-NWJ-0

Dear Mr. Patel:

This is regarding our June 19 through July 17, 2009 inspection of your pharmaceutical manufacturing facility, Sunrise Pharmaceutical, Inc., located at 665 E. Lincoln Avenue, Rahway, New Jersey. The inspection identified significant violations of the Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. These violations cause your drug products to be adulterated within the meaning of section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with CGMP regulations.

In addition, you manufacture a number of prescription drugs without approved applications. As described below, these drugs are unapproved new drugs, and by introducing them into interstate commerce you are in violation of 21 U.S.C. 355(a) (section 505(a) of the Act). These drugs are also misbranded under 21 U.S.C. 352(f)(1) (section 502(f)(1) of the Act).

We have reviewed your firm's responses of July 27, September 17, and November 18, 2009, and note that they lack sufficient corrective actions.

Specific violations observed during the inspection include, but are not limited, to the following:

CGMP Violations

1. Your firm has not established laboratory control mechanisms, including any change, and has failed to document quality control unit review and approval at the time of performance [21 CFR 211.160(a)]. For example,

   a. Out-of-specification (OOS) humidity levels for the controlled room temperature stability chamber were noted on January 27, March 17, and April 5 and 6, 2009. Investigations and corrective actions were not conducted at the time to address these out-of-specification results. During the inspection, however, the Quality Unit presented back-dated service requests to investigators as evidence of proper OOS result handling when in fact, no actual service requests were initiated.

   b. Investigation report #05072009 dated May 7, 2009, was initiated following a power failure during the coating of Senna & Docusate Sodium Film Coated Tablets, 8.6mg/50mg, lot 0904004. According to the report, the lot was inspected for peeled film tablets during May 8-26, 2009; however, the corrective actions and disposition of drug product were approved by the Quality Unit on May 7, 2009.

Regarding the above examples, the corrective action in your July 27, 2009 response states, "The employees involved will be retrained and warned tha a future recurrence will have zero tolerance resulting in severe action, including possible immediate termination." Your response fails to describe the specific type of training that will be provided and how the effectiveness of the training will be evaluated.

This is a repeat observation from the February and August 2007 inspections.

2. Your firm does not have adequate written procedures for production and process control designed to assure that your drug products have the identity, strength, quality, and purity that they purport or are represented to possess [21 CFR 211.100(a)].

For example, the validation studies for Guaifenesin and Dextromethorphan HBr 400mg/20mg Caplets are inadequate in that they do not demonstrate that the manufacturing process is reproducible. Specifically, one of your three validation lots, S0712012 (manufactured December 21, 2007), failed th blend uniformity test specifications. This same lot was blended for an additional 10 minutes without the review and approval of the Quality Unit. In addition, the validation protocol was not approved until April 2008, which is four months after the validation lot SO712012 was manufactured.

In your July 27, 2009 response, you promised to retrain your employees. However, we are concerned that this same commitment was made in the past for other deficiencies. Please specify the type of training that will be offered and how retraining will prevent recurrence of violations.

In your September 17, 2009 response, you provided an amendment to the validation report which referenced an additional validation lot (S0908003) of Guaifenesin and Dextromethorphan HBr 400mg/20mg Caplets. This additional lot was manufactured to fulfill your protocol requirements. However, your response does not specifically address: a) the blend uniformity failure for validation lot S0712012; b) whether the mixing time is a critical process parameter; and c) your rationale for concluding that your process is validated. You have not demonstrated that your manufacturing process is in a sufficient state of control and capable of reproducing acceptable product.

In addition, Section 5.4.2, Sampling Requirements, in your Process Validation Protocol, PVP-2000M-122T-04, states that **(b)(4)** tablets should be collected at **(b)(4)** for analytical testing. However, 10 tablets were collected from 14 sampling locations for a total of 140 tablets in lot S0908003. You

response does not address this apparent deviation from your protocol. Also, be advised that the degree of validation sampling (e.g.,number and frequency) and testing should be more extensive (than routine production) in order to provide sufficient statistical confidence of quality within a batch and between batches. Please address your confidence level when sampling a total of 140 tablets from a lot of **(b)(4)** tablets (protocol batch size).

Your response also fails to address the additional mixing of validation lot S0712012. We reviewed the amendment to your Process Validation Report, dated June 23, 2009, regarding the 10 additional minutes of mixing time (for a total **(b)(4)** of minutes). Your amendment states that "All Lots tested were complying with tolerance's set." However, your amendment further states that your total mixing time (i.e., established tolerance) was **(b)(4)** minutes as per your batch records and that the "Additional 10 minutes time has no impact on product Quality." Please provide the total mixing time established in the validation protocol and specifically, address any deviation from this established specification during the manufacture of the validatio lot S0712012. Also, provide your rationale for concluding that your validation data supports an additional 10 minutes of mixing time.

In addition, periodic process verification is essential for ensuring that a manufacturing process continues to be reproducible.

3. Your firm does not have master production and control records that justify variation in the amount of components necessary for the preparation of the dosage form [21 CFR 211.186(b)(4)].

For example, some of your products were formulated with excess amounts of active pharmaceutical ingredient (API). Specific instances include an excess of Dextromethophorphan HBr API in Guaifenesin and Dextromethorphan HBr Tablets, a excess of Colchicine API in Colchicine Tablets, and an excess of Hyoscyamine Sulfate API in Hyoscyamine Sulfate Subligual Tablets. You failed to provide documented scientific justification to explain why the excess API is necessary. In addition, you deemed the excess amounts as necessary due to "process loss;" however, none of these losses were documented.

Your July 27,2009 response states 'The master formulas justify whenever overages are used, i.e., moisture or solvent compensation." This response is inadequate because it does not address why excess amounts of API are needed for moisture or solvent compensation, or manufacturing process losses when charging the APIs used in drug product manufacturing. Your process is not considered to be in an adequate state of control when excess API (than as required in your batch records) is routinely used by your firm. To ensure proper formulation, you must document and justify the need for any excess amount of a component in each batch record.

4. Your firm has not established an adequate written testing program designed to assess the stability characteristics of your drug products in determining appropriate storage conditions and expiration dates since your program does not include reliable, meaningful, and specific test methods [21 CFR 211.166(a)(3)].

Specifically, some of your firm's analytical methods have not been validated to demonstrate that they are stability indicating. In other instances, test methods that you claim to be stability indicating are inadequate or not followed by your firm. For example,

a. A stability indicating test method has not been developed and validated for Senna & Docusate Sodium tablets.

b. Stability indicating test methods are developed, but not validated, for Guaifenesin and Dextromethorphan HBr Tablets, and impurity specifications have not been established for the finished product release or stability samples. as required by 21 CFR 211.160(b).

c. Validated stability indicating test methods are established, but are not followed, to analyze impurity levels for Phenazopyradine HCI Tablets, Bisacodyl Tablets, and **(b)(4)**. Further, impurity specifications have not been established for any of the aforementioned finished product release testing or stability samples as required by 21 CFR 211.160(b).

Your September 17, 2009 response did not include the following: a) specifications; b) allowable levels of impurities; or c) test results regarding impurity testing for Bisacodyl tablets. We note your response states that your firm has discontinued manufacturing of **(b)(4)** and Phenazopyradine HC Tablets.

Your November 18, 2009 response included method validation impurity testing results for Senna & Docusate Sodium Tablets and the Guaifenesin & Dextromethorphan drug products. However, your response did not state whether the impurity specification of Not More Than (NMT) **(b)(4)** noted in the method validation report, will be used during routine testing or stability testing in the future.

5. Your firm has not followed the written procedures for reprocessing batches that do not conform to standards or specifications for ensuring that the reprocessed batches conform with all established standards, specifications, and characteristics [21 CFR 211.115(a)].

For example, your firm did not follow SOP SMP-07, "Performance, Documentation and Approval of Reprocessing Operation," after Guaifenesin and Dextromethorphan HBr Caplets, validation lot S0712012, failed blend uniformity testing. A reprocessing master batch record was not prepared to reprocess the batch as per your SOP. Instead, production personnel remixed and resampled the lot, after which passing results were obtained and the lot was released.

The corrective action in your July 27, 2009 response indicates that employees will be retrained on existing procedures. This response is inadequate because it fails to describe when and how the employees will be retrained.

6. Your firm has not exercised appropriate controls over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel [21 CFR 211.68(b)].

For example, your firm lacks systems to ensure that all electronic data generated in your Quality Control laboratory is secure and remains unaltered. All analysts have system administrator privileges that allow them to modify, overwrite, and delete original raw data files on the **(b)(4)** used **(b)(4)** in the High Performance Liquid Chromatography (HPLC) units. There are no procedures that address the security measures in place for generation and modification of electronic data files for these instruments used for raw material, in-process, finished product and stability testing. In addition, your firm's review of laboratory data does not include a review of an audit trail or revision history to determine if unapproved changes have been made.

Your September 17, 2009 response states that you replaced the **(b)(4)** HPLC systems operating on **(b)(4)** software with **(b)(4)** new qualified HPLC units from **(b)(4)** software. This validation information will be reviewed at the next inspection. In addition, your response is inadequate because it lacks a retrospective evaluation of the data from the former HPLC units. This will prevent an alteration of data prior to implementation of your corrective actions. Further, your response does not address security procedures to ensure that the data generated using the new HPLC units is secure and remains unaltered.

This is a repeat observation from the February and August 2007 inspections.

Misbranded and Unapproved New Drugs

New drug and misbranding violations for prescription drug products

In addition to the CGMP violations, you manufacture and market unapproved new drugs in violation of the Act at your facility at your facility at 665 E. Lincoln Avenue in Rahway, New Jersey. Based on the information collected during the inspection, you manufacture the following prescription drugs, including but not limited to:

- Colchicine Tablets, 0.6 mg
- Hyoscyamine Sulfate Tablets, USP, 0.125 mg
- Hyoscyamine Sulfate Orally Disintegrating Tablets, 0.125 mg
- Hyoscyamine Sulfate Sublingual Tablets, 0.125 mg

The above products are drugs within the meaning of Section 201 (g) of the Act, [21 U.S.C. 321 (g)] because as demonstrated by their labeling, they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are "new drugs" within the meaning of Section 201 (p) of the Act [21 U.S.C. 321 (p)] because they are not generally recognized as safe and effective for their labeled uses. Under Sections 301 (d) and 505(a) of the Act [21 U.S.C. 331 (a), (d) and 355(a)] a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. 355(b) or (j)] is in effect for the drug. Based on our information, there are no FDA-approved applications on file for these drug products.

Additionally, the above products are misbranded because, as prescription drugs, adequate directions cannot be written for them so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for use as required under Sections 502 (f)(1) of the Act [21 U.S.C. 352(f)(1)] and because the products lack required approved applications, they are not exempt from this requirement unde 21 CFR 201.115. The introduction or delivery for introduction into interstate commerce of these products without approved new drug applications violates Section 301 (a) and (d) of the Act [21 U.S.C. 331 (a) and (d)].

New drug and misbranding violations for retail OTC drug products

Based on the information collected during the inspection, you manufacture and package for retail sale the following finished OTC drug products, including but not limited to:

- Sunrise Pharmaceutical, Aspirin, 325 mg, Pain Reliever Enteric Safety Coated, 100 Tablets
- Sunrise Pharmaceutical, Aspirin, 325 mg, Pain Reliever Enteric Safety Coated, 1000 Tablets
- Sunrise Pharmaceutical, Bisacodyl USP, 5 mg, Laxative, Enteric Sugar Coated, 100 Tablets
- Sunrise Pharmaceutical, Bisacodyl USP, 5 mg, Laxative, 1000 Enteric Sugar Coated Tablets
- **(b)(4)** Bisacodyl Tablets, USP, 5 mg, Delayed-Release Tablets Enteric Coated, 100 Tablets
- **(b)(4)** Bisacodyl Tablets, USP, 5 mg, Delayed-Release Tablets Enteric Coated, 1000 Tablets
- **(b)(4)** (Bisacodyl USP), Comfort Coated Stimulant Laxative, 5 mg, 100 Tablets (distributed by **(b)(4)**)
- **(b)(4)** Enteric Coated Stimulant Laxative (Bisacodyl USP), 5 mg, 100 Tablets (distributed by **(b)(4)**)
- Sunrise Pharmaceutical, Guaifenesin, 400 mg, Expectorant, 100 Tablets
- **(b)(4)** Guiafenesin, 400 mg, Expectorant, 100 Tablets (distributed by **(b)(4)**)
- Sunrise Pharmaceutical, Guaifenesin, 400 mg, Dextromethorphan HBR 20mg, Expectorant/Antitussive, 30 Tablets
- **(b)(4)**, Diphenhydramine HCL Capsules, USP, 50 mg, Antihistamine, 100 Capsules
- **(b)(4)** Diphenhydramine HCL Capsules, USP, 50 mg, Antihistamine, 1000 Capsules
- **(b)(4)** Diphenhydramine HCL Capsules, USP, 25 mg, Antihistamine, 1000 Capsules
- Sunrise Pharmaceutical, Aspirin, 81 mg, Pain Reliever Adult Low Dose, Enteric Safety Coated, 120 Tablets
- Sunrise Pharmaceutical, Aspirin, 81 mg, Pain Reliever Adult Low Dose, Enteric Safety Coated, 1000 Tablets
- Sunrise Pharmaceutical, Senna, 8.6 mg, Docusate Sodium, 50 mg, Natural Vegetable Laxative plus Stool Softener, 60 Tablets
- **(b)(4)** Natural Vegetable Laxative Plus Stool Softener, 100 Tablets
- **(b)(4)** Natural Vegetable Laxative Plus Stool Softener, 100 Tablets
- **(b)(4)** Docusate Sodium, Stool Softener Plus Laxative, 100 Tablets
- **(b)(4)** Docusate Sodium, Stool Softener Plus Laxative, 1000 Tablets

The above products are drugs within the meaning of section 201(g) of the Act, [21 U.S.C.321 (g)] because as demonstrated by their labeling, they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases.

Further, the three **(b)(4)** Diphenhydramine HCL Capsule products manufactured and packaged by Sunrise Pharmaceuticals as noted above for use as antihistamines are "new drugs" within the meaning of Section 201(p) of the Act [21 U.S.C. 321(p)] because they are not generally recognized as safe and effective for their labeled uses. Specifically, OTC drug products intended for use as OTC antihistamines with an active ingredient of diphenhydramine HCL, are subject to the requirements of the final monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use at 21 CFR Part 341. The labeling for all three diphenhydramine HCL products state the following indications for uses: "temporarily relieves· hay fever or other upper respiratory allergies like: • runny nose· sneezing ·watery eyes· itchy nose or throat". However, the fina monograph does not allow for the use of antihistamines to relieve hay fever or other upper respiratory allergies, rather the permitted uses are for temporary relief of such symptoms listed on your products label (i.e. runny nose, sneezing, watery eyes, itchy nose or throat) "due to hay fever ... or other upper respiratory allergies ...."[emphasis added] (21 CFR 341.72(b)).

Therefore, the three **(b)(4)** Diphenhydramine HCL products described above are "new drugs" as defined by section 201 (p) of the Act, 21 U.S.C. 321 (p) and 21 CFR 310.3(h), because the labeled uses are not in accordance with the Antihistamine Final Monograph (21 CFR 341.72). Additionally, none of the three diphenhydramine HCL products are the subject of an approved new drug application. Because the three **(b)(4)**Diphenhydramine HCL products above are new drugs and not the subject of an approved new drug application, the current marketing of these products in the United States violate sections 301(d) and 505(a) of the Act (21 U.S.C. 331(d), 355(a)).

Several of the products listed above are also misbranded. Specifically, both Sunrise Pharmaceutical Aspirin 325 mg Enteric Safety Coated drug products (100 and 1000 tablets) are misbranded under sections 201 (n) and 502(a) and (f) of the Act because both products' labeling have the Reye's Syndrome warning as the third warning under the 'Warnings" section, whereas, under 21 CFR 201.315(h)(2), the Reye's Syndrome warning is require to be "the first warning statement under the heading 'Warnings'" (see also 21 CFR 201.315(h)(4)).

In addition, the following products are misbranded under 502(c) and 502(e)(1)(A)(iii) because the inactive ingredients are not listed in alphabetical order, as required under 502(e)(1)(A)(iii) and 21 CFR 201.66(c)(8):

- Sunrise Pharmaceutical, Aspirin, 325 mg, Pain Reliever Enteric Safety Coated, 100 Tablets
- Sunrise Pharmaceutical, Aspirin, 325 mg, Pain Reliever Enteric Safety Coated, 1000 Tablets
- Sunrise Pharmaceutical, Bisacodyl USP, 5 mg, Laxative, Enteric Sugar Coated, 100 Tablets
- Sunrise Pharmaceutical, Bisacodyl USP, 5 mg, Laxactive, 1000 Enteric Sugar Coated Tablets
- **(b)(4)** Bisacodyl Tablets, USP, 5 mg, Delayed-Release Tablets Enteric Coated, 100 Tablets
- **(b)(4)** Bisacodyl Tablets, USP, 5 mg, Delayed-Release Tablets Enteric Coated, 1000 Tablets
- **(b)(4)** Diphenhydramine HCL Capsules, USP, 50 mg, Antihistamine, 100 Capsules
- **(b)(4)** Diphenhydramine HCL Capsules, USP, 50 mg, Antihistamine, 1000 Capsules
- **(b)(4)** Diphenhydramine HCL Capsules, USP, 25 mg, Antihistamine, 1000 Capsules
- Sunrise Pharmaceutical, Aspirin, 81 mg, Pain Reliever Adult Low Dose, Enteric Safety Coated, 120 Tablets
- Sunrise Pharmaceutical, Aspirin, 81 mg, Pain Reliever Adult Low Dose, Enteric Safety Coated, 1000 Tablets
- Sunrise Pharmaceutical, Senna, 8.6 mg, Docusate Sodium, 50 mg, Natural Vegetable Laxative plus Stool Softener, 60 Tablets
- **(b)(4)** Natural Vegetable Laxative Plus Stool Softener, 100 Tablets
- **(b)(4)** Natural Vegetable Laxative Plus Stool Softener, 1000 Tablets
- **(b)(4)** Docusate Sodium, Stool Softener Plus Laxative, 100 Tablets
- **(b)(4)** Docusate Sodium, Stool Softener Plus Laxative, 100 Tablets

Furthermore, all of these products that do not list the inactive ingredients in alphabetical order--except the diphenhydramine HCL products--also have an inactive ingredients header under the "Drug Facts" that states "May contain the following inactive ingredients" (emphasis added). The use of "May contain" in the inactive ingredients header does not comport with the appropriate heading under 21 CFR 201.66(c)(8) and makes the product misbranded under 502(c) of the Act. Also, the use of "May contain" to list inactive ingredients indicates that there are inactive ingredients that may or may not be present in the product. Such labeling that lists all ingredients as potentially alternative ingredients is false and misleading and makes the product misbranded under 502(a) because it fails to identify which inactive ingredients are present in the product (See FDA's "Guidance for Industry Labeling OTC Human Drug Products", May 2009, for guidance on labeling inactive ingredients that may or may not be contained).

Also, for your information, the formatting of the "Drug Facts" section on several of your OTC products is inconsistent with the requirements under 21 CFR 201.66. For example, the "Aspirin, 325 mg, Pain Reliever Enteric Safety Coated, 1000 tablets" product does not have its "Drug Facts" header in larger font than the rest of the "Drug Facts" (see 21 CFR 201.66(d)(2).

Misbranding of bulk packaged finished OTC drug products intended for repackaging

In addition, based on the information collected during the inspection, you also manufacture the following OTC drugs that are finished OTC products shipped with bulk package labeling for repackaging, including but not limited to:

- Aspirin Film Coated White Tablets, 325 mg
- Aspirin Enteric Coated Orange Tablets, 325mg
- Phenylephrine Hydrochloride Film Coated Red Tablets, 5mg
- Phenylephrine HCL F/C Red Tablets, 10mg
- Bisacodyl E/C Orange Tablets, 5mg
- Chlorpheniramine Maleate Yellow Tablets 4mg
- Guaifenesin Caplets
- Guaifenesin & Dextromethorphan HBr. Caplets, 400mg & 20mg
- Chewable Aspirin Orange Flavor Tablets 81 Mg
- Diphenhydramine HCL Capsules, 50mg
- Diphenhydramine Hydrochloride Capsules, 25mg
- Aspirin Enteric Coated Yellow Tablets, 81 mg
- Senna & Docusate sodium F/C Orange Tablets, 8.6mg & 50mg
- Senna & Docusate sodium F/C Red Tablets, 8.6mg &50mg
- Aspirin Enteric Coated Peach Tablets, 81 mg

Based on documentation and bulk package labeling collected for the above products, the products are finished OTC drug products labeled for repackaging. As finished OTC drug products, the above OTC drug products once introduced into interstate commerce for repackaging, unless exempte under 21 CFR 201.150, must meet all drug labeling requirements described in section 502 of the Act (21 USC 352) and in 21 CFR 201, including the "Drug Facts" labeling requirements under 21 CFR 201.66. Based on documentation collected there is no evidence that the operators of the establishments where the drugs are to be repackaged are part of Sunrise Pharmaceuticals nor is there evidence that there are labeling agreements in place with such operators, and, in turn, neither exemption under 21 CFR 201.150(1) or (2), respectively, are met. Therefore, the above products, which only have bulk package labeling, are misbranded: (1) under section 502(c) of the Act because none of the outer container labeling contains "Drug Facts" required by 21 CFR 201.66; (2) under section 502(e)(1)(A)(iii) because the inactive ingredients are not listed; (3) under 502(f) of the Ac because there are not adequate directions for use and warnings; and (4) under sections 502(a) and 201(n) of the Act because the bulk labeling is misleading by conveying the products are exempt from required FDCA labeling.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. We note that several deficiencies were cited in the August 2007 inspection and correction actions were promised. The current inspection found that promised corrective actions have not occurred and the same deficiencies exist at your firm. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure compliance wit all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action withou further notice including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending drug applications listing you facility, until the above violations are corrected. FDA may re-inspect to verify corrective actions have been completed.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction. Additionally your response should state if you no longer manufacture or distribute the drug products manufactured at this facility, and provide the date(s) and reason(s) you ceased production.

We also request that you outline the action you are taking to discontinue the marketing of the unapproved drug products at your facility, or any other applicable drug which you may market. Also please note that if you are no longer marketing these products, you must update the Drug Listing files in accordance with 21 CFR 207.30(a)(2).

Your response should be sent to the following address: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

/s/

Diana Amador-Toro
Director, New Jersey District

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