Division of Pharmaceutical Quality Operations I
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WARNING LETTER
CMS 535005

December 19, 2017

VIA UPS NEXT DAY AIR

Paul F. Devine, CEO/President
C.O. Truxton, Inc.
136 Harding Avenue
Bellmawr, NJ 08031

Dear Mr. Devine:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, C.O. Truxton, Inc. ("Truxton"), at 136 Harding Avenue, Bellmawr, New Jersey (FEI 2220338), from April 17 to June 1, 2017.

This warning letter summarizes significant violations of current good manufacturing practices (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

In addition, your firm mislabeled drug products, causing them to be misbranded under section 502(b)(2) and 502 (e)(1)(A)(ii) of the FD&C Act, 21 U.S.C. 352(b)(2) and 21 U.S.C. 352(e)(1)(A)(ii). By introducing adulterated and misbranded drugs into interstate commerce you are in violation of section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

We reviewed your June 14, 2017, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

CGMP Violations

1. Your firm failed to establish a quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a)).

Your firm failed to establish a quality control unit for your drug repackaging operation and you lacked written procedures for production or quality unit responsibilities.

You did not address this observation in your response. You stated that "some items were not addressed, as they should not have been done and will not be done by C.O. Truxton Inc., in the future." We are unclear as to what specific items you referred to in your response.

In your response to this letter, provide your procedure detailing the responsibilities of the quality control unit, and outline your repackaging operations with their corresponding procedures. In addition, specify which operations your firm has ceased to perform and the dates on which such operations were halted.

2. Your firm failed to establish and follow written procedures to assure that correct labels and packaging materials are used for drug products (21 CFR 211.130).

Your firm performs repackaging and labeling operations but did not have written procedures governing the application of packaging and labeling materials to your drug products. You incorrectly labeled a container filled with Phenobarbital tablets 30 mg as Phenobarbital tablets, USP 15 mg (schedule IV) lot 70952A. In the affidavit collected during the inspection, you stated, "I have no records to show the repackaging operation."

You did not address this observation in your response. In your response to this letter, provide your plan, including written procedures, to ensure compliance with CGMP for all drug repackaging activities in which you engage.

3. Your firm failed to establish and follow adequate written procedures describing the handling of all written and oral complaints regarding a drug product (21 CFR 211.198(a).

Your firm lacked an adequate procedure for handling complaints. You received a complaint regarding a bottle labeled as Phenobarbital Tablets USP (15 mg, 1000 count), lot 70952A. The product received was actually Phenobarbital Tablets USP (30 mg, 1000 count.) You sold this drug product to both human and animal clinics. Your firm did not maintain a record of the complaint or investigate it to determine the cause of the labeling mix-up.

In response to our inspection, you drafted and submitted a complaint handling procedure. However, this procedure is inadequate because it lacks adequate provisions to investigate the complaints you receive.

In your response to this letter, provide your complaint handling procedure, including cataloguing, tracking, and investigating complaints.

4. Your firm failed to establish a written distribution procedure to include a system by which each lot of drug product can be readily determined to facilitate its recall if necessary (21 CFR 211.150(b)).

Your firm lacked any procedures describing your drug distribution system. Your distribution system was deficient in that it could not differentiate between the lot number your firm assigns and the lot number assigned by the manufacturer, and therefore there is no product traceability if a recall is required. Our investigator observed that neither your receiving or shipping records included the lot numbers of products you received and shipped.

In your response, you stated that, moving forward, only Phendimetrazine manufactured and packaged by **(b)(4)** will bear the Truxton label. Your response was inadequate because you did not address your firm's lack of traceability for your repackaged drug products.

In your response to this letter, provide your drug distribution and tracking procedures for your repackaged drug products.

5. Your firm failed to establish and follow a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).

You had no data to support the expiration date of Phenobarbital tablets, USP 15 mg (schedule IV) lot 70952A repackaged from original container-closure system (500-count bottle size) to a new container- closure system (1000-count bottle size). You had not performed stability testing of the drug product in the new container-closure system and you did not have any supporting stability data to support the use of the new container-closure system. In addition, you were unable to provide documentation to show that the container-closure system used to repackage drug products was identical or equivalent to their original container-closure systems.

You did not address this observation in your response. In your response to this letter, provide your evaluation of any other drug products that may have been repackaged into a different container-closure system, and the procedures and controls you have in place to assess stability of the drug products in their new container-closure systems. Include your corrective action plan if you find drug products that are unstable in the new container-closure system.

Misbranding Violations

Your phenobarbital tablets were labeled as containing 15 mg of Phenobarbital but in fact the tablets contained 30 mg of Phenobarbital. Further, as labeled, the Phenobarbital 15 mg tablets are misbranded drugs within the meaning of section 502(b)(2) of the FD&C Act, 21 U.S.C. 352(b)(2), in that the labels for these packaged drug products did not bear an accurate statement of the quantity or the contents in terms of weight, measure, or numerical count. Also, your Phenobarbital 15 mg tablets are misbranded within the meaning of section 502(e)(1)(A)(ii) of the FD&C Act, 21 U.S.C. 352(e)(1)(A)(ii), in that the drug product is labeled as Phenobarbital 15 mg, and the proportion of the active ingredient in each phenobarbital tablet is 30 mg of Phenobarbital (as identified by tablet markings)

In addition to the CGMP violations, your firm repackaged mislabeled drugs in violation of the FD&C Act at your facility. Based on the information collected during the inspection, you mislabeled the following prescription drug, including, but not limited to: Phenobarbital Tablets 30 mg mislabeled as Phenobarbital Tablets 15 mg.

As labeled, the Phenobarbital Tablets are misbranded drugs within the meaning of section 502(a) of the FD&C Act, 21 U.S.C. 352(a), in that the labels are false.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Correct the violations cited in this letter promptly. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other federal agencies from awarding contracts. Until these violations are corrected, we may withhold approval of pending drug applications listing your facility, or remove your current misbranded drugs listing information from public databases such as the online NDC Directory. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your firm's response to the U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rdFloor, Parsippany, New Jersey 07054. Refer to CMS case 535005 when replying. If you have any questions about this letter, please contact CDR Liatte Krueger, Compliance Officer, at (973) 331-4933.

Sincerely,

/S/

Diana Amador-Toro
Division Director/OPQ Division 1
New Jersey District Office