Transox Inc 6/8/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District
Southeast Region
60 Eighth St.
Atlanta, GA 30309

Telephone: 404-253-1163
FAX: 404-253-1201

June 8, 2015

VIA UPS

WARNING LETTER
(15-ATL-11)

David McClendon, Owner
Trans Ox, Inc.
3469 Leaphart Road
West Columbia, SC, 29169

Dear Mr. McClendon:

During our November 13, 2014, through November 20, 2014, inspection of your pharmaceutical manufacturing facility, Trans Ox, Inc., at 2543 Morningside Drive, Suite A, West Columbia, South Carolina, an investigator from the U.S. Food and

Drug Administration (FDA) identified significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug product 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.

We have reviewed your firm's response in detail. It lacks sufficient corrective actions.

Our investigator observed specific violations during the inspection, including, but not limited to, the following:

1. For each batch of drug product, your firm must have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, before release (21 CFR 211.165(a)). Your firm does not have appropriate documentation.

During our inspection of your facility, we documented multiple incidents of inaccurate batch production records containing erroneous statements, including results that were not derived from analytical testing or from your supplier's Certificates of Analysis (CoAs).

According to your batch production records, your results were obtained from a "Post Fill Purity Test." The records are labeled "ANALYTICAL RESULTS OBTAINED BY USING THE **(b)(4)** OXYGEN ANALYZER." However, on November 13, 2014, the FDA investigator observed cobwebs between the portable **(b)(4)** Oxygen Analyzer and the adjacent wall. The general manager stated that your firm does not use the **(b)(4)** Oxygen Analyzer, which directly contradicts your batch production records.

Further, on November 13, 2014, our investigator reviewed a number of batch records and asked you why all the analytical results reported on these batch production records were identical. Although your batch production records indicate that analytical results were obtained from the **(b)(4)** Oxygen Analyzer, you responded to the investigator's question by stating that the values were actually obtained from your supplier's CoAs. However, the values reported on multiple batch production records disagree with the CoAs for those lots.

a) For instance, the batch production record for your lot 011514 (supplier lot 515244) states your purity test result on the **(b)(4)** Oxygen Analyzer was 99.9%. In contrast, the CoA for supplier lot 515244, dated December 23, 2013, states 99.74% purity.

b) Similarly, the batch production record for your lot 032614 (supplier lot 515240) states your purity test result on the **(b)(4)** Oxygen Analyzer was 99.9%. In contrast, the CoA for supplier lot 515240, dated March 20, 2014, states 99.84% purity.

In your response, you stated that you have created a Policy and Procedure Manual, which includes Batch Production and Control Records and an Equipment Calibration Schedule. However, your response does not include any retrospective reconciliation of batch production records and CoAs, or testing of lots currently in stock or in distribution. Retrospective assessment is essential to determining if batches released prior to your implementation of new procedures met purity specifications.

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

The FDA investigator requested records related to your Quality Control Unit (QCU) to review during the inspection. Your general manager was unfamiliar with QCU terminology. After the investigator explained QCU terminology, the general manager stated that he is “probably” the QCU. We note that essential functions of the QCU were not carried out, including the review of all information related to each batch prior to arriving at a batch disposition decision. For example, there was no secondary/QCU review of the batch production records with questionable data as detailed above.

Your response included creating a Policy and Procedure Manual, appointing a Compliance Officer, and appointing a Quality Control Officer. This response is insufficient. You have not provided details of required training for each person carrying out QCU functions. Your response also fails to describe steps you have taken to determine how the safety, efficacy, and quality of your products may have been affected by your previous lack of a QCU.

Conclusion

These examples are serious CGMP violations. Your quality system does not adequately ensure the accuracy and integrity of the data generated at your facility to support the safety, effectiveness, and quality of the drug products you manufacture.

We strongly recommend that you hire a qualified third party auditor/consultant to help you come into compliance with CGMP regulations and statutory requirements.

As part of your corrective action and preventive action plan, describe the actions you have taken or will take, such as contacting your customers; recalling product; conducting additional testing; enhancing systems for monitoring, investigating, and responding to deviations, complaints, and returns; and/or other steps, to assure the

quality of the product manufactured under the violative conditions discussed above.

In addition, as part of your corrective action and preventive action plan, describe the actions you have taken or will take to prevent recurring CGMP violations. These may include revising procedures, implementing new controls, training or re-training personnel, and/or other steps.

The violations cited in this letter are not intended as an all-inclusive list of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above, for preventing their recurrence, and for preventing other violations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without 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 your facility, until the above violations are corrected. FDA may re-inspect to verify that corrective actions have been completed.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct deviations. Include an explanation of each step taken to prevent the recurrence of deviations and copies of supporting documentation. If you cannot complete corrective action within fifteen (15) working days, state the reason for the delay and the date by which you will have completed the correction.

Send your reply to:

Ms. Marie Mathews
Compliance Officer
Food and Drug Administration, Atlanta District
60 Eighth Street
Atlanta, GA 30306

If you have any questions about this letter, please phone Ms. Mathews at (404) 253-1279 or fax to (404) 253-1201.

Sincerely,
/S/
Ingrid A. Zambrana
District Director

CC:
Mr. Robert Scully, GM
Trans Ox, Inc.
3469 Leaphart Road
West Columbia, SC, 29169

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