Adamson Analytical Laboratories Inc 8/2/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

August 2, 2016

WL # 38-16

Ms. Vicky T. Seto
Laboratory Director and Owner
Adamson Analytical Laboratories, Inc.
220 Crouse Drive
Corona, CA 92879-8093

Dear Ms. Seto:

The U.S. Food and Drug Administration (FDA) inspected your drug contract testing laboratory, Adamson Analytical Laboratories Inc. at 220 Crouse Drive, Corona, Calif., from August 4-14, 2015.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, 21 CFR parts 210 and 211, and significant deviations from CGMP for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drugs 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).

We acknowledge receipt of your firm's September 25, 2015, response.

Our investigators observed specific violations and deviations including, but not limited to, the following.

Finished Product: CGMP Violations

1. Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records (21 CFR 211.68(b)).

Specifically, your high performance liquid chromatography (HPLC) and gas chromatography (GC) data acquisition systems did not have sufficient controls to prevent deletion or alteration of raw data files. During the inspection, our investigators observed that your laboratory personnel use a shared password to access the HPLC **(b)(4)** computer system and that your GC **(b)(4)** computer system requires no password for access.

In addition, multiple instruments had no audit trail function to record information about each analytical test, such as:

- type of injection
- date and time
- identity of analyst
- reason for action taken (for example, modifying a record)

This is a repeat observation from our February 7, 2013, inspection. In 2013, you committed to augmenting the security of your computer systems within six months. However, based on our 2015 inspection, it appears that you have not made appropriate corrective actions such as installing audit trails and ensuring that analysts have unique user names and passwords for your computerized systems.

It is essential that your firm keep track of all changes made to your electronic data. The use of audit trails for computerized analytical instrumentation helps to ensure that all additions, deletions, or modifications of information in your electronic records are authorized. It also allows you to verify the quality and integrity of the electronic data your contract testing laboratory generates for your customers.

We acknowledge your commitment to install and configure appropriate electronic controls to ensure that access to your computerized systems and data is restricted to authorized personnel with access rights specified for each individual. However, your response is inadequate as you did not provide an action plan describing the interim security measures in place prior to your installation of electronic controls. Your response also lacked details regarding the type of electronic controls to be installed, and you did not describe how you will evaluate the effectiveness of these computerized system changes.

2. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to

appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b))

Specifically, your quality control unit failed to ensure completeness and accuracy of your laboratory procedures, analytical data, and test results. For example:

- You did not detect that your secondary reference standards for oxymetazoline hydrochloride were not appropriately qualified as required by your firm's standard operating procedure (SOP), **(b)(4)**.
- You reviewed and approved laboratory notebooks with missing data such as HPLC chromatograms and assay calculations.

API: CGMP Deviation

3. Failure of your quality unit to ensure that materials are appropriately tested and the results are reported.

During the inspection, our investigators discovered that your firm failed to appropriately qualify the secondary reference standard for avobenzone API required by your firm's SOP, **(b)(4)**.

In your response, you state that you retrained the quality control unit personnel, and that you appropriately qualified your secondary standards. Your response is inadequate because you did not provide a risk assessment of the lots tested with the unqualified secondary reference standards. You used these secondary reference standards for analysis of your customer's API. Your failure to appropriately qualify your secondary reference standards calls into question the accuracy of the analytical results you provide to your API customers.

In response to this letter, provide a plan describing how your quality control unit will effectively exercise its responsibilities. Include how your quality control unit will verify that all of your secondary reference standards have been appropriately qualified. Also, include how your quality control unit will verify that your laboratory records include complete electronic raw data. Provide assurance that your corrective actions will effectively prevent the types of failures described above from recurring in the future. In addition, include a risk assessment regarding your practice of testing drugs with unqualified secondary reference standards.

Conclusion

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

FDA considers contractors as extensions of the manufacturer's own facility. Your failure to comply with CGMP may affect the quality, safety, and efficacy of the drugs you test for your clients. It is essential that you understand your responsibility to operate in full compliance with CGMP, and to inform all of your customers of significant problems or deviations encountered during the testing of these drugs.

After you receive this letter, you have 15 working days to respond to this office in writing. Specify what you have done since our inspection to correct your violations

and deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 days, state your completion date and reasons for delay.

Correct the violations and deviations cited in this letter promptly. Failure to promptly correct these violations and deviations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations and deviations in this warning letter may also prevent other Federal agencies from awarding contracts.

Until these violations and deviations are corrected, we may withhold approval of pending drug applications listing your facility. We may also refuse requests for export certificates. We may re-inspect to verify that you have completed your corrective actions.

Send your reply to:

CAPT Larry Howell, Acting Director
Compliance Branch
U.S. Food & Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612
Attn: Dr. Raymond W. Brullo, Compliance Officer

Please identify your response with FEI 3000204955.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Los Angeles District Director