U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Aubrey Inc. 5/16/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2606
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 16, 2011

W/L 41-1

Aubrey A. Woodroof, Ph.D., M.B.A., CEO
Aubrey Inc.
5930 Sea Lion Pl, Ste. 100
Carlsbad, CA 92010-6661

Dear Dr. Woodroof:

During an inspection of your firm located in Carlsbad, California on January 31 through February 04, 2011, investigator(s) from the United States Food and Drug Administration (FDA) determined that your firm manufactures AWBAT (Advanced Wound Bioengineered Alternative Tissue) devices and variations of the AWBAT device. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from Stephan W. Moss, President dated February 24, 2011 concerning our investigator's observations noted on the FDA 483, List of Inspectional Observations, that was issued to Mr. Moss. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to adequately ensure the device conforms to defined user needs and intended uses, as required by 21 CFR 820.30(g).

For example, your firm did not establish by objective evidence that the Advanced Wound Bioengineered Alternative Tissue (AWBAT) temporary wound dressing meets the **(b)(4)** shelf life product specification as specified in Product Requirements Document (PRD), **(b)(4)** Revision A, section 6.1.12.

We reviewed the response and conclude that it is not adequate because your firm has not provided any supportin data showing AWBAT meets its **(b)(4)** shelf life specification.

2. Failure to adequately verify design output meets design input requirements, as required by 21 CFR 820.30(f).

For example, your firm did not establish by objective evidence that your AWBAT temporary wound dressing meet specified requirements following exposure to storage and shipping conditions specified in Product Requirements Document (PRD), **(b)(4)**, Revision A, sections 11.2 - 11.4.

We reviewed the response and conclude that it is not adequate because your firm has not provided any supportin data showing AWBAT meets its specifications after exposure to shipping, storage, relative humidity, or altitude conditions as mentioned in **(b)(4)** Revision A, sections 11.2 - 11.4.

3. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspectio and test that the process is validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a).

For example, your firm allows for e-beam sterilization of AWBAT products up to **(b)(4)** days after completion of the spraying/sealing process; however, your firm has no sterilization validation data supporting the **(b)(4)** day post processing timeframe.

We reviewed the response and conclude that it is not adequate because your firm has not provided any supportin data showing evaluations of bioburden levels for sprayed/pouched product during the **(b)(4)** day specified holdin period, Your initial E-Beam sterilization validation determined that sprayed/pouched product does not have bacteriostatic or fungistatic properties.

4. Failure to verify or where appropriate, validate according to 21 CFR 820.75, changes to a specification, method process, or procedure before implementation, as required by 21 CFR 820.70(b).

For example, your firm sterilized three lots of sprayed/sealed AWBAT product, eleven, five, and one days, after the **(b)(4)** day holding period specification.

We reviewed the response and conclude that it is not adequate because your firm has not provided any supportin data justifying the process deviation.

5. Failure to establish and maintain adequate procedures for acceptance of incoming product, as required by 21 CFR 820.80(b).

For example, visual inspections performed during the receiving inspection for Nylon component lots C014H and C0141, identified failures and both non-conforming lots were released after additional samples were taken and tested. Your firm has not established a retest provision in your firm's Nylon Receiving Test procedure.

We reviewed the response and conclude that it is not adequate because your firm proposes a correction and not a corrective action.

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90(a).

For example, your firm did not follow Non-Conforming Material procedure **(b)(4)** Revision C, when your visual inspection performed during the receiving inspection for Nylon component lots C014H and C014I identified failures and both non-conforming lots were released after additional samples were taken and tested. There was no Material Review Report completed to document the non-conforming material for review and disposition by the Material Review Board.

We reviewed the response and conclude that it is not adequate because your firm proposes a correction and not a corrective action.

7. Failure to establish and maintain procedures to control environmental conditions, as required by 21 CFR 820.70(c).

For example, annual environmental monitoring performed on 01/06/2010 and 01/13/2011 did not include measuring airborne particulates of **(b)(4)**µm size as required by your firm's Controlled Environment Requirements procedure, **(b)(4)** Revision B.

We reviewed the response and conclude that it is not adequate because your firm proposes a correction and not a corrective action.

8. Failure to validate software used as part of production or the quality system for its intended use according to an established protocol, as required by 21 CFR 820.70(i).

For example, your firm did not validate use of an Excel spreadsheet used to calculate the Moisture Vapor Transmission Rate (MVTR) per test procedure **(b)(4)** Revision B.

Your response to this observation appears to be adequate.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which these activities will be completed.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Please send your reply to:

U.S. Food and Drug Administration
Attn: Blake Bevill
Director, Compliance Branch
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506

If you have questions regarding any issues in this letter, please contact Dr. Raymond W. Brullo, Compliance Officer at (949) 608-2918.

Sincerely,
/S/

Alonza E. Cruse
District Director
Los Angeles District

Links on this page: