Inspections, Compliance, Enforcement, and Criminal Investigations

Innovative Med Inc. 3/19/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4417

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

March 19, 2013

WL # 31-13

Ben M. Khalaj, Chief Executive Officer
Innovative Med Inc.
4 Autry Way, Unit B
Irvine, CA 92618-2708

Dear Mr. Khalaj:

During an inspection of your firm located in Irvine, California on October 03 through 09, 2012, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Celluderm as well as other physical medicine therapeutic products. 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 to affect the structure or any function of the body.

Our inspection revealed that the Celluderm is adulterated under 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 manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice [cGMP] of the Quality System Regulation found in Title 21, Code of Federal Regulations [CFR], Part 820 as follows:

Your firm's product labeling procedure has not been adequately implemented as required by 21 CFR § 820.120. Specifically, you lack documented approval for your vacuum therapy device; labeling software is not defined in your standard operation procedure; and device history records lack the primary label/labeling.

Your firm's device master record has not been adequately implemented as required by 21 CFR § 820.181. Specifically, your device master records for vacuum therapy device lack complete specifications and you lack drawings or instructions for assembly of your IM-CELL-E or IM-CELL-T devices.

Your firm has not adequately implemented acceptance procedures as required by 21 CFR § 820.80. Specifically, you perform a pump pressure inspection but the final inspection procedure does not specify which tools or equipment will be used in performing inspections.

Your firm's Internal Audit Procedure was not adequately implemented as required by 21 CFR § 820.22. Specifically, two internal auditors audited areas in their direct control which does not comply with your procedure.

During the inspection, FDA learned that your firm is distributing the Celluderm as a therapeutic massager to end users with knowledge and approval of claims promoted by your distributor **(b) (4)**. A therapeutic massager is identified by 21 CFR 890.5660 as "an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains." Therapeutic massagers are Class I and exempt from premarket notification requirements subject to the limitations in 21 CFR 890.9. See 21 CFR 890.5660. Devices of this generic type work by delivering vibration and contain moving components on them that deliver massage, or knead the tissue. However, these claims are made on page 3 of the Celluderm Operating Manual, which represent new intended uses:

"Celluderm System on its own is a highly effective method of stimulating the lymphatic system and reducing congestion…drains the fat that has been released into the blood and lymphatic system and attacks the top layer of the fat, breaking up the congestion that contributes to sluggish lymphatic flow".

"... break up fat congestion pulling the breakdown of fats through the softened cell membrane and into the interstitial fluid"

"Celluderm treatment progressively wears down congestion by manipulating body tissue using a vacuum suction massage."

Because the Celluderm is distributed with new intended uses, it exceeds the limitations of exemption described in 21 CFR 890.9 and is not exempt from premarket notification.

Because the Celluderm exceeds the limitations of exemption described in 21 CFR 890.9 and there is no premarket clearance or approval for the device, the Celluderm is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81 (b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Your firm 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Blake Bevill, Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19701 Fairchild, Irvine, California 92612. Refer to the Unique Identification Number (CMS Case # 372459) when replying. If you have any questions about the contents of this letter, please contact: Dr. Raymond W. Brullo, Compliance Officer at (949)-608-2918 or raymond.brullo@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA, including obtaining the necessary premarket clearance or premarket approval for the intended uses of all of your devices as defined by 21 CFR 801.4. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Alonza E. Cruse, Director
Los Angeles District

Cc:
Patrick Kennelly, Acting Branch Chief
California Department of Public Health
Food and Drug Branch
PO Box 997435
1500 Capitol Avenue, MS-7602
Sacramento, CA 95899-7413
Attn: FDA Correspondence

Close Out Letter

- Innovative Med, Inc. - Close Out Letter 2/13/14[1]

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U.S. Food and Drug Administration
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Silver Spring, MD 20993

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