Inspections, Compliance, Enforcement, and Criminal Investigations

Oxyhealth, LLC 8/8/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 8, 2013

WARNING LETTER

VIA UNITED PARCEL SERVICE

Samir Patel
President
OxyHealth, LLC
10719 Norwalk Blvd.
Santa Fe Springs, California 90670

Re: Hyperbaric Chambers
Refer to Case # 406207 when replying to this letter.

Dear Mr. Patel:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing hyperbaric chambers in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device, because it is 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.

The Office of Compliance, in FDA's Center for Devices and Radiological Health, reviewed the website "http://www.oxyhealth.com/" and found that your firm markets the following hyperbaric chambers:

- Solace 210
- Respiro 270
- Vitaeris 320
- Quamvis 320

Hyperbaric chambers are Class 2 devices under Title 21, Code of Federal Regulations, Part 868.5470, which require submission of an application for clearance under section 510(k) of the Act, 21 U.S.C. § 360(k).

The listed products are 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 products are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the products 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) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm[1]. The FDA will evaluate the information that your firm submits and decide whether the 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.

Please direct your response to Carl Fischer at the Food and Drug Administration, White Oak Building 66, Rm 3526, 10903 New Hampshire Ave., Silver Spring, MD 20993, facsimile at 301-847-8138. We remind you that only written communications are considered official.

Finally, you should know that this letter is not intended to be an all-inclusive list of your firm's violations. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations and take prompt actions to correct the violations and bring your firm's products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Close Out Letter

- OxyHealth, LLC - Close Out Letter 4/8/14[2]

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

1. https://wayback.archive-it.org/7993/20170112190419/http://www.fda.gov/MedicalDevices/%20DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm
2. /7993/20170112190419/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm392569.htm