Inspections, Compliance, Enforcement, and Criminal Investigations

Clearwater Products, LLC, 3/10/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FI 32751

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-10-14

March 10, 2010

Robert L. Bolden
President
Clearwater Products LLC
5910 Pine Hill Road, Unit #9
Port Richey, Florida 34668

Dear Mr. Bolden:

During an inspection of your firm located in Port Richey, Florida, on August 24, 2009 through August 25, 2009, a investigator from the United States Food and Drug Administration (FDA) determined that your firm manufacture the Water Lily, a colonic irrigation system. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), this product is a medical 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 is intended to affec the structure or function of the body.

Our inspection revealed that your device is misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), i that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

Fai!lure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

> For example, during the August 24 through 25, 2009 inspection of Clearwater Products, you stated to the FD/ investigator that your firm lacks written MDR procedures.

We have reviewed your response and have concluded that it is inadequate because you have not addressed the regulatory requirements to develop, maintain, and implement written MDR procedures.

Our inspection also revealed that your device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do 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 (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under sectior 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your 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 satisfiec 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 hnp://www.fda.gov /cdrh/devadvice/3122.htm1. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Additionally, a review of our records revealed that the Water Lily is listed as an Enema Kit for cleaning purposes Consequently, your device is misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, 21 U.S.C. 360. In addition, the device was not included in a list required by section 510(j), 21

U.S.C. 360m, and a notice or other information respecting the device was not provided to the FDA as required b section 510(k), 21 U.S.C. 360(k).

We have reviewed your response and have concluded that it is inadequate. You state that **(b)(4)** will assist you in obtaining a 510(k) for the Water Lily and that they will work with you in setting up current good manufacturin practices. FDA has not received any additional responses to the observations from the FDA inspection since this September response. You have not informed us of any specific plan or provided information for immediate corrections and systemic corrective actions to handle the deficiencies noted during the FDA inspection.

This inspection also revealed that the device is 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, its 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 you dated September 4, 2009, concerning our investigator's observations noted on the Form FDA 483, Inspectional Observations that was issued to you. 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 establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a)(1).

For example, you have no written design control procedures for the Water Lily including not having an adequately established design history file and not having documentation of requirements for tubing dimensions, carbon filters, and UV light for the Water Lily.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.30(a)(1) nor have you informed us of any specific plan or provided evidence of immediate corrections and systemic corrective actions.

2. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).

For example, you do not have a written corrective and preventive action procedure.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.100(a) nor have you informed us of any specific plan or provided evidence of immediate corrections and systemic corrective actions.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a).

For example, you do not have a written complaint procedure.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.198(a) nor have you identified any systemic corrective actions for the evaluation of complaints.

4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

For example:

1. You have not assured that **(b)(4)**, supplier of the "FDA PVC tubing" used in the manufacture of the Water Lily, has completed the validation study of the extrusion process used to manufacture the "FDA PVC tubing". You have not adequately established the quality requirements that must be met by **(b)(4)**.

2. You have not documented that "FDA PVC tubing, supplied by **(b)(4)**, meets requirement of durometer of 85, being safe for use with drinking water and that is "surgical grade".

3. You have not documented that the temperature sensor used in the Water Lily was calibrated with a sensor that is NIST certified, as claimed by the supplier of the sensor, **(b)(4)**.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.50 nor have you informed us of any specific plan or provided evidence of immediate corrections and systemic corrective actions.

5. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a).

For example:

1. You have no written procedures for the final inspection of the finished device, the Water Lily.

2. You have no written procedures for the incoming inspection of the fiberglass "table", a component of the Water Lily.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.80(a) nor have you identified any systemic corrective actions to ensure that inspections, tests, and other verification activities are being documented.

6. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is i compliance with the established quality system requirements, as required by 21 CFR 820.22.

For example, your firm lacks written internal audit procedures and has not completed an internal audit.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.22 nor have you informed us of any specific plan or provided evidence of immediate corrections and systemic corrective actions.

7. Failure to retain records required by this part for a period of time equivalent to the design and expected life o the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer, as required by 21 CFR 820.180(b).

For example, your firm documents the final inspection of the Water Lily on a checklist, but discards the checklist after each Water Lily device is shipped.

We have reviewed your response and have concluded that it is inadequate. Your firm has not adequately addressed the requirements of 21 CFR 820.180(b) nor have you informed us of any specific plan or provided evidence of immediate corrections and systemic corrective actions.

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. Also, 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 preven these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Salvatore N. Randazzo, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions about the content of this letter please contact Mr. Randazzo at (407) 475-4712.

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.

Sincerely yours,

/s/

Emma R. Singleton
Director, Florida District

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