Inspections, Compliance, Enforcement, and Criminal Investigations

Premium Dental, LLC 1/14/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-4906

January 14, 2010

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mark Neuman
President
Prerrllum Dental, LLC
1451 Route 88, Suite 11
Brick, NJ 08724

10-NWJ-04

Dear Mr. Neuman:

During an inspection of your firm located in Brick, New Jersey, on July 29, 2009 through August 5, 2009, investigators from the United States Food and Drug Administration (FDA) determined that your firm is the initial distributor and importer for the Dr. Brux® My Night Guard. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act ("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 are intended to affect the structure or function of the body.

At the close of the inspection, FDA Investigators discussed with you objectionable conditions observed during the inspection. A Form FDA-483 was issued. On August 24, 2009 and September 25, 2009, your firm's attorney, Andrew Citron, provided written responses to the Form FDA-483. The violations and your responses are discussed below.

The Act requires initial distributors and importers of medical devices to obtain marketing clearance or approval from FDA before they may offer them up for sale. This requirement

protects the public health by helping to ensure that new medical devices are shown to be either both safe and effective or substantially equivalent to other devices already legally marketed in the United States.

The FDA inspection 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, 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 responses from Andrew Citron dated August 24, 2009, and September 25, 2009, concerning our investigator's observations noted on the Form FDA 483, List of 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 procedures for implementing corrective and preventive action (CAPA). 21 CFR § 820.100(a).

Specifically, your firm has no CAPA procedures that include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

We have reviewed your responses pertaining to CAPA procedures and have concluded that they were inadequate because of the following:

a. Your CAPA procedure, Revision A, does not specify that you will verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device as required by 21 CFR § 820.100(a)(4). For example, your firm needs to perform effectiveness checks in order to verify that the corrective and preventive actions were effective as to the intended purpose of the action and that new issues or concerns are not introduced.

b. No training records were provided to show that your CAPA procedures were implemented and are being followed by your firm.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. 21 CFR § 820.198(a).

Specifically, your firm has no complaint handling procedures and/or files to receive, document, process in a uniform and timely manner, and evaluate complaints to determine whether they represent events required to be reported to FDA under 21 CFR § 803.

We have reviewed your responses pertaining to complaint handling procedures. Although the procedures appear to be adequate, the effective implementation of the procedures cannot be verified at this time.

Our inspection also revealed that the device is misbranded within the meaning of section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)] in 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. These violations include, but are not limited to, the following:

1. Failure to develop, maintain, and implement written MDR procedures for internal systems and the documentation and recordation of required information, as required by 21 CFR § 803.17.

Specifically, your firm has not developed, maintained, and implemented written MDR procedures for internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements.

We have reviewed your responses pertaining to MDR procedures and have concluded that they were inadequate. For example, your procedures do not describe how you will:

a. Determine when an event meets the criteria for reporting events to FDA as required by 21 CFR §803.50;

b. Provide all information reasonably known as required by 21 CFR § 803.50(b)(1)(i)(ii)(iii);

c. Provide complete reports to FDA as required by 21 CFR §803.50(b)(3);

d. Conduct a complete investigation of each event to determine the cause of the event as required by 21 CFR §803.50(b)(3);

e. Include information in reports as required by 21 CFR §803.52;

f. Submit supplemental reports to the FDA within the timeframes required by 21 CFR §803.56; and,

g. Document and maintain records required by 21 CFR §803.18.

We note that section "4.10 Reports of Corrections and Removals" in your document "Medical Device Reporting" pertains to reporting requirements for corrections and removals. It is our view that merely referencing the regulation in your SOP statement, "If a 'risk to health' determination is made, refer to reporting requirements of 21 CFR 806," does not constitute an adequate procedure because there is no way to verify its effective implementation.

Our inspection also revealed that the 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 section 502(o) 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 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.

Furthermore, our inspection revealed that the device is misbranded within the meaning of section 502(o) of the Act [21 U.S.C. § 352(o)] in that a notice or other information respecting the device was not provided to the FDA as required by section 510(k) of the Act [21 U.S.C. § 360(k)]; the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act [21 U.S.C. § 360]; and the device was not included in a list required by section 510(j) of the Act [21 U.S.C. § 360(j)]. You can obtain the registration form from our website at http://www.fda.gov.

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 FDA

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 prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action 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: Robert J. Maffei, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey, 07054. If you have any questions about the content of this letter, please contact Mr. Maffei at 973-331-4906.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) 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 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/

Diana Amador-Toro
District Director
New Jersey District Office

cc. Roberto Turchetti
President
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