



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Combination Products
5600 Fishers Lane (HF-7)
Room 14B-03
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

March 11, 2003

[redacted]
Dentsply International
[redacted]

Re MTAD Root Canal Cleanser Solution
Request for Designation
Our file: RFD 2003.004/C
Dated: February 6, 2003
Received and Filed: February 10, 2003
Amended: February 12, 2003

Dear [redacted]

The Food and Drug Administration has completed its review of your request for designation (RFD) for MTAD Root Canal Cleanser Solution (MTAD), which was filed by the Office of the Ombudsman on February 10, 2003. On February 11, 2003, the Office of the Ombudsman determined that MTAD is a combination product. Your RFD was subsequently transferred to the Office of Combination Products (OCP) for determination of the product's primary mode of action and for assignment of a lead agency center for premarket review and regulation.

Description of the Product

According to the RFD, MTAD is a root canal cleanser and irrigant composed of [redacted] that is indicated in the cleansing of the root canal during endodontic therapy. As we discussed in a telephone conversation on March 10, 2003, the [redacted] will be purchased from a GMP-compliant pharmaceutical manufacturer, and will be provided at [redacted] concentration in the final product. MTAD's primary mode of action is stated to be the cleansing of the root canal and removal of the smear layer "by breaking down the layer into component particles that can be easily lifted away by the action of the fluid surrounding them." This action is purported to be a result of the [redacted] with assistance from the [redacted] component. MTAD's secondary mode of action is stated to be antibacterial. As furthermore described in the RFD, the combined action of the product's components is intended to fully remove the smear layer and kill bacteria, while individually the components would only partially

achieve such effect. [

] You recommend that the product be assigned to the Center for Devices and Radiological Health (CDRH).

#### Product Classification: Combination Product

When used during endodontic therapy in combination with files and reamers, root canal cleansers perform cleansing functions by [ for easier instrumentation, and flushing the loosened debris from the canal. The Office of the Ombudsman has determined that the root canal cleanser, without the addition of the [ component, is a device, while the [ component is a drug. Since MTAD is comprised of both device and drug components, it is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(g)] and 21 CFR § 3.2(e)(1). In accordance with 21 CFR § 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's "primary mode of action."

#### Assignment of Lead Center

We have determined that the primary mode of action of the combination product is attributable to the mechanical cleansing (device) properties of the MTAD solution, while the [ (drug) component has a secondary (antibacterial) role. Consequently, we are assigning this combination product to CDRH for premarket review and regulation under the medical device provisions of the Act. This assignment is also consistent with the Intercenter Agreement between the Center for Drug Evaluation and Research (CDER) and CDRH (see sections VII.A.2 and VIII.A.5).

Any clinical investigations of the product should be conducted in accordance with the investigational device exemptions (IDE) regulation (21 CFR Part 812). The manufacture of the [ drug substance will be subject to current good manufacturing practices for drugs in accordance with section 501(a)(2)(B) of the Act. The combination product will be subject to the Quality System Regulation (21 CFR Part 820) and Medical Device Reporting (21 CFR Part 803), consistent with the requirements for other products regulated under medical device authorities.

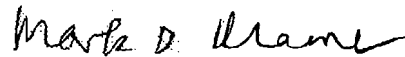
CDRH's Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices will have lead responsibility for the premarket review and regulation of MTAD solution. CDRH may consult with CDER, as necessary, in the review and regulation of the product. For further information about review requirements, please contact Dr. Kevin Mulry in the Dental Devices Branch at (301) 827-5283. Please include a copy of this letter with your initial submission to CDRH.

You may request reconsideration of the classification or assignment of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact the undersigned at (301) 827-3390. Finally, the

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Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by e-mail at [combination@fda.gov](mailto:combination@fda.gov).

Sincerely yours,



Mark D. Kramer  
Director  
Office of Combination Products

cc: Dr. Kevin Mulrv