DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food and Drug Administration
Rockville MD 20857

August 17, 1999

Mr. P. Jeffery Lehn
Director, Corporate Compliance
and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872

Re: Request for Designation
Seal & Protect™ Protective Sealant for Exposed Dentine
Our file: RFD 99.009

Dear Mr. Lehn:

The Food and Drug Administration (FDA) has completed its evaluation of the above-referenced request for designation, received and filed on June 21, 1999.[1] The request covers Dentsply's Seal & Protect™ Protective Sealant for Exposed Dentine.

Seal & Protect™ is described as a "light-curing dental varnish." Its composition and method of manufacture are described in detail in the submission and are incorporated here by reference. According to the request, the chemical composition is identical to Dentsply's Prime & Bond® Universal Dental Adhesive™ (K983966), with the addition of C 3 (an antimicrobial).

Seal & Protect™ is "designed to protect exposed dentine areas, both mechanically and by way of an antimicrobial agent."[2] The product is indicated for use to reduce abrasion and erosion of exposed cervical dentine, C 3 and treat hypersensitive cervical areas. The company has stated that it has no intention of promoting any one of these claims as a stand-alone indication for use.[3]

[1] 21 CFR Part 3
[2] Request for Designation, page 6
[3] Statement made during an August 12, 1999 telephone conversation between Ms. Jean Stenger, Regulatory Affairs Associate at Dentsply and Ms. Tracey Forfa of the Office of the Ombudsman.

You recommended that the product be designated a combination product with the primary review responsibility assigned to the Center for Devices and Radiological Health (CDRH). This recommendation is based, in part, on your assertion that the primary mode of action of the product in strengthening and coating the cervical dentine is that of a device.

We have carefully considered the information in your request, reviewed the pertinent provisions of the Intercenter Agreement (ICA) between the Center for Drug Evaluation and Research (CDER) and CDRH, and discussed the issues raised with staff in the two centers. Based on our review, we are designating CDRH as the lead center for premarket review of the product. The product will be subject to review under the medical device provisions of the Federal Food, Drug, and Cosmetic Act.[4] Our decision is based on the view that the product is a combination product whose primary mode of action is attributable to its physical properties as a dental varnish or sealant. The decision is consistent with sections VII.A.2. and VIII.A.5. of the CDER – CDRH ICA, which assigns CDRH responsibility for premarket review of any drug – device combination product in which the primary intended purpose fulfills a device function.

The Division of Dental, Infection Control, and General Hospital Devices in the Office of Device Evaluation, CDRH, will be the primary review group. The Division will conduct its review in collaboration with CDER staff, particularly with respect to the proposed use of triclosan in the product. For further information, contact Susan Runner, D.D.S., Branch Chief, Dental Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation, CDRH, 9200 Corporate Boulevard (HFZ-480), Rockville, MD 20850, or by telephone at 301-443-8879. Please include a copy of this letter in your initial submission to CDRH.

Please note that the designation decision applies solely to the product when promoted for use as a dental varnish or sealant. Should Dentsply propose to market the product predominantly for its antimicrobial properties, a second request for designation should be submitted.

If you have any questions concerning this matter, please contact Tracey Forfa, of this office, at 301-827-3390.

Sincerely yours,

Steven H. Unger
Acting Chief Mediator and Ombudsman

cc. Susan Runner, D.D.S. (HFZ-480)

[4] 21 U.S.C. § 360c et. seq