DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Combination Products
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

March 7, 2008

Genevieve de Villedon
Produits Dentaires Pierre Rolland
17, Avenue Gustave Eiffel
ZI du phare – 33708 Merignac cedex France

Re: Request for Designation
Hemostasyl
Our file: RFD080003
Dated: Undated
Received and Filed: January 8, 2008

Dear Ms. de Villedon:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for Hemostasyl. The Office of Combination Products (OCP) received and filed the RFD on January 8, 2008. We have determined that the product is a combination product, and we have assigned it to the Center for Devices and Radiological Health (CDRH) as the lead agency center for premarket review and regulation because CDRH regulates other combination products that present similar safety and effectiveness questions with regard to the combination product as a whole.

Description of the Product

According to the RFD, the product consists of two two-gram syringes containing the Hemostasyl paste and forty application cannulas. The Hemostasyl paste consists of a hydrogel, composed of [redacted], anhydrous colloidal silica, and purified water, that is combined with aluminum chloride, blue colorant, and flavor. It is intended to control moderate bleeding occurring during routine dental procedures. According to the RFD, Hemostasyl controls bleeding through two mechanisms of action. One is achieved due to the viscosity and adhesiveness of the paste, which allow the hydrogel to have a clogging effect; the other is due to astringent properties of the aluminum chloride, which result in contraction of tissues and blood vessels.

You assert that the product is a combination product, and propose that the agency assign the product to CDRH for premarket review and regulation because you believe its primary mode of action (PMOA) is achieved by the clogging effect of the hydrogel.

Product Classification: Combination Product

We have determined that, because the product is comprised of both device (hydrogel) and drug (aluminum chloride) components, it is a combination product within the meaning of section 503(g) of the Act and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1).[1] In accordance with section 503(g) of the Act and 21 CFR section 3.4, assignment of a lead Center to conduct the review of a combination product is based on FDA's determination of the product's primary mode of action.

Assignment of Lead Center: CDRH

We have considered the information in the RFD and discussed the issues with staff from CDRH and the Center for Drug Evaluation and Research. This product has two modes of action. Both device and drug components act to control bleeding. We cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of your combination product. Both actions significantly contribute to the product's intended use to control moderate bleeding, and neither is clearly subordinate to the other.

Because we could not determine with reasonable certainty which mode of action provides the most important therapeutic action of the product, the agency next considered, in accordance with 21 CFR 3.4(b), whether there is a component in FDA that regulates other combination products that present questions of safety and effectiveness similar to those raised by this combination product as a whole. In this case, CDRH regulates other combination products that present questions of safety and effectiveness similar to those raised by Hemostasyl. In particular, as noted in your RFD, CDRH regulates at least one other product intended for hemostatic and gingival retraction uses consisting of a paste that includes aluminum chloride. Accordingly, we are assigning the combination product to CDRH for premarket review and regulation under the device provisions of the Act.

CDRH's Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, Dental Devices Branch will have lead responsibility for the combination product's premarket review and regulation. For further information on how to proceed, please contact the Branch Chief, Susan Runner, DDS, MA at 240-276-3776. 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 to ask any

[1] We note that the literature suggests that, in addition to aluminum chloride, two other ingredients in Hemostasyl, [redacted] might have coagulative effects. If FDA determines that the product acts differently than you have described in your RFD, a separate determination may be necessary.

questions about this letter, please contact John Barlow Weiner, JD, Acting Product Classification Officer at (301) 427-1941. Finally, the 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 email at combination@fda.gov.

Sincerely,

Thinh Nguyen
Director
Office of Combination Products

cc: Susan Runner