DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Food and Drug Administration
Rockville MD 20857

April 21, 2004

Ms. Denise Swift
Director of Regulatory Affairs
Sinclair Pharmaceuticals Limited
Borough Road
Godalming
Surrey GU7 2AB
United Kingdom

Re: Request for Designation
Decapinol® Oral Rinse
Our file: RFD 2004.013
Dated: March 3, 2004
Received and Filed: March 4, 2004

Dear Ms. Swift:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) you submitted on behalf of Sinclair Pharmaceuticals Limited for Decapinol® Oral Rinse. The RFD was received and filed by FDA's Office of Combination Products on March 4, 2004.

Description of the Product

According to the RFD, Decapinol® is an anti-plaque rinse containing the [redacted] The aqueous solution also contains [redacted] It is intended to help [redacted] and treat gingivitis and [redacted] by inhibiting plaque formation on teeth. Decapinol® is intended to be administered as a mouthwash twice daily after brushing.

As explained in the RFD, gingivitis [redacted] are caused by plaque build-up on teeth. Plaque is formed when bacteria interact with the thin film of salivary proteins and glycoproteins that coat the teeth, known as the acquired pellicle. Bacteria molecules interact with the acquired pellicle through non-specific forces. Once bacteria attach or adhere to the pellicle-coated tooth surface, they multiply and form plaque.

The acquired pellicle has a net negative surface potential. Decapinol® is a [redacted] Therefore, according to the RFD, Decapinol® is [redacted] to the acquired pellicle on the surface of the teeth and gums. According to the RFD, Decapinol® prevents plaque build-up on teeth by acting as a physical barrier between plaque-causing bacteria circulating in the oral cavity and the

acquired pellicle. In the presence of Decapinol®, fewer bacteria are able to adhere to the acquired pellicle.

The RFD recommends that Decapinol® be designated as a prescription medical device for regulation by the Center for Devices and Radiological Health (CDRH).

Product Classification: Device

We have considered the information in the RFD and discussed the issues with staff from CDRH, the Center for Drug Evaluation and Research (CDER), and the Office of Chief Counsel.

We agree with the RFD that Decapinol® appears to achieve its primary purposes by acting as a physical barrier that prevents the interaction of bacteria with the acquired pellicle. Therefore, we conclude that Decapinol® is appropriately regulated by CDRH as a device. Based on the information provided, Decapinol® meets the definition of a device because it does not achieve its primary intended purposes through chemical action within or on the body of man, nor is it dependent on being metabolized for the achievement of its primary intended purposes.[1]

CDRH's Division of Anesthesiology, General Hospital, Infection Control and Dental will be the reviewing division. CDRH will consult with CDER as appropriate in its review of Decapinol®. CDRH will review Decapinol® under the device provisions of the act. Any clinical investigations of the product must be conducted under an investigational device exemptions (IDE) application in accordance with 21 CFR Part 812. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Dr. Susan Runner, Chief, Dental Devices Branch, at 301-827-5283 x117. Please include a copy of this letter with your initial submission to CDRH.

If you would like to discuss this matter further, or if you have any questions about this letter, please call me at 301-827-9229.

Sincerely,

Suzanne O'Shea
Product Classification Officer

cc: Susan Runner

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[1] A device is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; or intended to affect the structure or function of the body of man. A device may not achieve its primary intended purposes through chemical action within or on the body of man nor can it be dependent upon being metabolized for the achievement of its primary intended purposes. Section 201(h) of the act; 21 U.S.C. § 321(h).