DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2005

Ms. Denise Ström
Director, Regulatory Affairs
Sinclair Pharmaceuticals
Borough Road
Godalming
Surrey GU7 2AB
United Kingdom

Re: K041482 Evaluation of Automatic Class III Designation
Decapinol® Oral Rinse
Regulation Number: 21 CFR 872.5580
Classification: II
Product Code: NTO

Dear Ms Ström:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of Decapinol® Oral Rinse, which is used as an aid in the treatment of gingivitis by inhibiting bacterial adhesion to tooth surfaces. Decapinol oral rinse serves as an adjunct to normal mechanical oral hygiene where this has proved inadequate. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies Decapinol® Oral Rinse, and substantially equivalent devices of this generic type into class II under the generic name, Oral Rinse to Reduce Adhesion of Dental Plaque.

FDA identifies this generic type of device as: Oral Rinse to Reduce Adhesion of Dental Plaque: This device is intended to reduce by physical means, the presence of bacterial plaque on teeth and oral mucosal surfaces.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On January 24,2005, FDA filed your petition requesting classification of the Decapinol® Oral Rinse into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on January 14,2005, automatically classifying the Decapinol® Oral Rinse in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Decapinol® Oral Rinse into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition, FDA has determined that Decapinol® Oral Rinse, as described in the petition, can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

The risks associated with the use of this device type and measures identified to mitigate them include:

1. Risk: ineffective plaque reduction. Risk mitigations include thorough material characterization and the evaluation of device performance.

2. Risk: alteration of oral flora. The risk mitigation identified is the evaluation of device performance.

3. Risk: adverse tissue reaction (hard and soft tissue). Risk mitigations include thorough material characterization, the evaluation of device performance, and the evaluation of device biocompatibility.

4. Risk: toxicity. Risk mitigations include thorough material characterization and adequate device labeling.

5. Risk: improper use. The risk mitigation identified is adequate device labeling.

In addition to the general controls of the act, oral rinses used to reduce the adhesion of dental plaque are subject to the following special control: Class II Special Controls Document: Oral Rinse to Reduce Adhesion of Dental Plaque.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the device they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register.** A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Robert S. Betz, D.D.S. at 301-827-5283.

Sincerely yours,

Donna Bea
Director
Office of Device Evaluation
Center for Devices and
Radiological Health