

Volume I

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Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 2005D-0240
 Draft Guidance for Industry
 “Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention”
 Published in the Federal Register June 28, 2005
 Volume 70 Number 123, pp 37102-37103
 Comment: Cosmetic Claims for Oral Antiplaque Products

WhiteHill Oral Technologies, Inc., submits these comments in response to the publication by FDA of the Draft Guidance for Industry, “Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention” published in the Federal Register, June 28, 2005, Vol. 70 Number 123, pp. 38102-37103. WhiteHill manufactures products intended for use in the oral cavity, some marketed for cosmetic purposes and others for drug purposes. Representatives of WhiteHill participated extensively during the public hearings conducted by the Plaque Subcommittee.

In response to the proposed Guidance for Industry, which “focuses on plaque-induced gingivitis”, WhiteHill is submitting three separate and independent comments. (1) These comments address only the cosmetic claims that are applicable to oral antiplaque products. (2) Separate comments address the structure/function drug claim applicable to OTC oral antiplaque products, to help maintain good oral hygiene. (3) Separate comments address the

general reduction and prevention of oral health problems claims applicable to OTC oral antiplaque products.

WhiteHill agrees with the Division of Dermatologic and Dental Products, in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA), that antigingivitis claims are properly classified as drug claims. Because of its focus on gingivitis as a clinically significant endpoint, however, the FDA failed to consider the evidence presented to the Subcommittee regarding the cosmetic and drug claims justified by reduction of plaque, without consideration of any effect on gingivitis. These WhiteHill comments therefore focus solely on cosmetic benefits of significant reduction in dental plaque.

Considering the draft Guidance for Industry defines the term, gingivitis, as “plaque-induced gingival disease” that “responds well to oral hygiene and antimicrobial products,” it is disappointing and disconcerting to this member of the oral hygiene industry that the Draft Guidance does not expand on the role biofilms play in dental plaque; nor, except for a general reference to “oral hygiene,” does the draft Guidance address the critical role *physical removal of biofilms* plays in maintaining oral health. Accordingly, both of these are covered at length by WhiteHill in the three separate and independent comments included herewith.

WhiteHill manufactures a melt-emulsion of polydimethylsiloxane (silicone) in the food-grade surfactant poloxamer. As demonstrated in scientific studies submitted by WhiteHill to the Subcommittee and in response to the proposed draft Guidance for Industry and the proposed monograph with respect to structure/function and general disease prevention claims, the combination of polydimethylsiloxane and poloxamer is effective in achieving a significant reduction in dental plaque. This combination was determined by the Subcommittee to be

Category I for safety (pages 32274-32275). Because the combination is not intended for use to prevent gingivitis, it was placed in Category III for this use.

I. Action Requested

WhiteHill requests that FDA recognize that antiplaque claims limited solely to cosmetic benefits are cosmetics, and not drugs, within the definitions set forth in the FD&C Act, and therefore are not subject to the antiplaque/antigingivitis OTC drug monograph, nor to the draft Guidance for Industry.

II. The Definition of a Cosmetic Under the FD&C Act

Section 201(i)(1) of the FD&C Act defines the term “cosmetic” to mean an article:

“intended ... for cleansing, beautifying, promoting attractiveness, or altering the appearance.”

As the FDA Chief Counsel has recently stated in an authoritative opinion letter (copy attached as Appendix A to these comments), “It is well settled that intended use is determined with reference to marketing claims” (page 3). The Chief Counsel pointed out that it is foreseeable that any product used on the human body will have some type of effect on the structure and function of the body, but this is not the determining factor for classifying products under the FD&C Act (pages 4-6). Accordingly, these comments focus on the cosmetic benefits of antiplaque products that make only cosmetic claims and that are not claimed or otherwise intended to have antigingivitis or any other disease activity or benefits and are outside: (a) the antiplaque/antigingivitis OTC drug monograph, and (b) the draft Guidance for Industry.

III. The Cosmetic Benefits of Plaque Reduction

Put simply, many consumers view dental plaque as nothing more than oral dirt. Just as we seek to remove dirt from other aspects of our daily lives, we seek to remove it from our teeth for purely cosmetic purposes -- for cleansing, beautifying, promoting attractiveness, and altering appearance.

The oral cavity is unique among all the exposed surfaces of the body. Only the oral cavity is self-evaluating, without depending upon the use of some other sensory organ or surface. You can feel or perceive your mouth with the mouth itself. There is no need for you to stroke the surface of the mouth with your fingers, as one would do to evaluate the cosmetic benefits of a moisturizer, or look in the mirror to see the shine that a cosmetic imparts to the hair. Your mouth itself can feel when there is too much plaque. Even more dramatic is the self-perception of mouth odor exacerbated by plaque build-up. Your mouth knows when it does not feel clean and the teeth do not feel smooth. We all want our mouths to feel clean and fresh. And the intimacy of the oral cavity makes it subject to the cosmetic judgments of colleagues, friends, and family.

The following discussion briefly describes some of the specific cosmetic benefits of plaque reduction.

A. Teeth Cleaning

An accumulation of dental plaque can readily be seen by people with normal vision. Teeth become dull where plaque has accumulated above the gum line. People want their teeth to be white and bright, not dull and dirty. Many products have been used to clean teeth by removing plaque. Some of these products are purely physical, such as a toothbrush or dental floss, and others are based on physical chemistry, such as ingredients in toothpaste and

mouthwash products. Still others can reduce the surface-free energy of the tooth so that newly forming plaque is less able to stick to the surface. Regardless of the mechanism of the cleansing action, the intended use -- cleaning the tooth to get rid of dull, unsightly plaque -- is purely cosmetic in nature.

B. Reduction in Mouth Odor

Plaque harbors bacteria that produce mouth odor. Reducing plaque reduces mouth odor in the same way that underarm deodorants reduce underarm odor. Odor reduction is a long-recognized cosmetic benefit.

C. Improved Mouth Feeling

Everyone wants to have teeth that feel clean. We all run our tongue over our teeth to feel how clean they are. We brush our teeth in the morning to make them feel cleaner. And we periodically go to the dentist for a professional cleaning, after which they feel like new. This perception of clean teeth is a clear cosmetic benefit.

D. Making Teeth More Beautiful

By reducing dull plaque on our teeth and concurrently reducing a source of mouth odor, we feel and look more beautiful and have greater assurance in our appearance. Excess plaque accumulation can also attract and bind the chromophores of tea, coffee, tobacco, wine, and some other foods. Reducing plaque therefore contributes to a reduction in the potential for tooth stains, another unequivocal cosmetic benefit. We all appreciate the beauty of a bright smile, and plaque reduction increases our confidence in flashing our teeth to the world.

E. Promotes Attractiveness

By improving the appearance of our teeth and helping to keep our breath fresh, as well as making our mouth feel fresher and cleaner, we are improving our own personal feeling of attractiveness. This falls squarely within the definition of a cosmetic.

F. Altering Appearance

Plaque reduction can brighten teeth and can help remove stains and thus improve the appearance of the teeth. As the Subcommittee recognized, dental plaque “may be combined with other materials such as food particles and sloughed epithelial cells” (page 32236). Reduction in plaque thus reduces the potential for this unattractive *materia alba*. This provides another cosmetic benefit.

IV. Cosmetic Claims Are Not Drug Claims

All of the above attributes fall within the statutory definition of a cosmetic. None falls within the statutory definition of a drug.

The Subcommittee concluded that all plaque claims should be regarded as drug claims, even if those claims are explicitly limited to cosmetic benefits. Not only is there no support in the FD&C Act for this position, as recognized by a footnote added to the Subcommittee report by FDA on page 32238, but there is no support in the record of this proceeding for such a position. No information of any kind was cited by the Subcommittee to support the contention that a carefully worded cosmetic claim suggests “a drug-like benefit” (page 32238). The Subcommittee did not rely upon documented scientific data or empirical evidence for this statement. The various types of cosmetic benefit claims outlined above can readily be worded in a way that is accurate, truthful, and not misleading. The First Amendment to the United States Constitution protects the right of the regulated industry to make such claims.

WhiteHill agrees with the Subcommittee that an unqualified antiplaque claim, with no reference to cosmetic benefit, is ambiguous and must therefore be regarded as both a drug and a cosmetic claim, and thus subject to the requirements for proof of antigingivitis effectiveness. Where an antiplaque claim is limited solely to cosmetic benefits, however, there is no factual or

legal basis for classifying it as a drug claim by the Subcommittee nor by the FDA in their draft Guidance for Industry.

The Subcommittee makes unsupported gratuitous comments questioning the cosmetic effectiveness of antiplaque products that are not represented for any drug purpose. The OTC Drug Review in general, and the antiplaque/antigingivitis OTC drug monograph proceeding and the draft Guidance for Industry apply only to drugs. Accordingly, data regarding the cosmetic effectiveness of antiplaque products were not requested in the FDA call-for-data, were in fact not submitted for consideration by the Subcommittee nor by the FDA, and are not relevant to the Subcommittee findings nor to the FDA's draft Guidance for Industry. The Subcommittee comments about cosmetic effectiveness, which are unsubstantiated and incorrect, are therefore of no relevance to this proceeding and should not be considered by the FDA in their draft Guidance for Industry.

V. Conclusion

For the reasons set forth above, WhiteHill requests that FDA, in the draft Guidance for Industry, recognize that antiplaque claims limited solely to the types of cosmetic benefits described above are cosmetics, and not drugs, within the definitions set forth in the FD&C Act, and therefore are not subject to the antiplaque/antigingivitis OTC drug monograph, nor to the provisions of the draft Guidance directed to Development and Evaluation of Drugs for Treatment or Prevention of Gingivitis.



Robert D. White