Appendix I

Regulatory Analysis Of The Cosmetic/Drug Status Of Antiplaque Claims

Appendix I

1.0 Regulatory Analysis Of The Cosmetic/Drug Status Of Antiplaque Claims

During 1993 and 1994, the Plaque Subcommittee debated the regulatory status of antiplaque claims, as well as the factual support for such claims. Representatives of CHPA and CTFA participated in these discussions and provided the Plaque Subcommittee with a great deal of information concerning what antiplaque products do, how they are labeled, how consumers perceive them and understand claims made for them, and their regulatory status. The associations demonstrated that, under the applicable statutory and regulatory provisions, as long interpreted by the courts and by FDA, a product with an antiplaque claim should be classified as a cosmetic, and not as a drug, so long as the claim is qualified by reference solely to the product's cosmetic benefits. CHPA and CTFA also showed that FDA consumer protection requirements regarding cosmetics are comparable to those applicable to OTC drugs and that FDA has ample powers to enforce these requirements.[1/]

Nevertheless on December 7, 1994, the Plaque Subcommittee voted to recommend to FDA that, in classifying OTC antiplaque products, all references to the control of dental plaque, or its equivalents, with or without qualification, will be

---

[1/] Past industry submissions to the Plaque Subcommittee concerning the drug/cosmetic status of antiplaque products include: Statement by Stephen H. McNamara, CHPA (August 1993); Statement by James H. Skiles, CTFA (August 1993); Statement by James H. Skiles, CTFA (December 1993); Statement by Stephen H. McNamara, CHPA (August 1993); Presentation of Plaque Statement Consumer Research conducted for CHPA/CTFA by Walker Research (June 1994); and Statement by Stephen H. McNamara, CHPA (December 1994).

interpreted as drug claims. The Subcommittee's recommendation has not yet been embraced or rejected by FDA[2]. As these comments will show, it is inconsistent with the FDC Act, FDA regulations, and Agency precedent.

1.1 Antiplaque Products Provide Cosmetic Benefits to Consumers

The link between plaque and disease states is complex. The Subcommittee states in its report that "It should be noted that the relationship between the quantity of plaque present and the degree of gingivitis is sufficiently complex such that reductions in plaque mass alone are inadequate to conclude that a therapeutic effect on gingivitis could be expected. Therefore, gingivitis must be measured directly."[3] Thus the Subcommittee itself recognized that antiplaque activity may not lead to therapeutic benefits in all cases.

The cosmetic benefits from the use of these products include cleaner and whiter teeth, less formation of unsightly tartar, cleaner feeling mouth, smoother feeling teeth and fresher breath. Antiplaque products significantly improve the ability of consumers to remove or prevent the buildup of plaque on their teeth. Plaque is a ubiquitous problem, and many consumers take, or wish to take, steps to prevent or reduce it. A consumer can remove much of the plaque by thorough flossing or rigorous brushing alone, but consumers do not floss and brush thoroughly enough to remove plaque

---

[2] This point is echoed by FDA in the ANPR on page 32238 where the Agency states "The legal opinions of this scientific panel in this area may not and do not necessarily reflect FDA's position."

completely. The remaining plaque continues to grow and accumulate immediately after these mechanical treatments. Antiplaque products augment brushing and flossing to facilitate the control of plaque. In its report, the Subcommittee also stated that, "It is also highly unlikely that the marginal control of bacterial deposits has a significant relationship to most, if not all, of the cosmetic claims."[4].

Oral care products making plaque-related claims may provide important cosmetic benefits to consumers. These benefits include cleaning teeth to help promote better mouth odor, mouth feel, and dental appearance. Cosmetic benefits, as defined by law, include "cleansing, beautifying, promoting attractiveness, or altering appearance."[5] In contrast, a drug is intended to prevent or treat disease or to affect the structure or function of the body. Thus, prevention or treatment of gingivitis is a drug claim. And if a product is represented as effective in removing plaque in order to prevent or treat gingivitis, that is also a drug claim. But, the mere use of the term "plaque" in labeling for a topical oral dosage form, such as a dentifrice or a mouthwash, does not necessarily create drug status. One must read a plaque claim in the context of a product's full labeling to determine the intended use of the product. This will classify the product as a drug, cosmetic, or cosmetic drug.

---

[3] 68 Fed. Reg. at 32237

[4] 68 Fed. Reg. at 32238

[5] 21 U.S.C. 321(i)(1).

1.2 The Marketing Status Of An Antiplaque As A Cosmetic, Drug, or Both Is Determined By The Product's Intended Use Based Upon Claims

1.2.1 The Legal Classification Of A Product As A Cosmetic, A Drug, Or Both Depends On The Intended Use Of The Product.

The distinction between a cosmetic and a drug derives from the definitions of the terms "cosmetic" and "drug" in the FDC Act. The term "cosmetic" is defined in section 201(i) of the Act as:

> "articles *intended* to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles *intended* for use as a component of any such articles; except that such term shall not include soap." 21 U.S.C. § 321(i) (emphasis added).

The term "drug" is defined, in pertinent part, in section 201(g)(i) of the Act as:

> "(B) articles *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) *intended* to affect the structure or any function of the body of man or other animals . . . ."21 U.S.C. § 321(g)(i) (emphasis added).

The definitions of "cosmetic" and "drug" are not mutually exclusive. An article may, depending on the uses that are claimed for it, be a cosmetic, or a drug, or both. Thus, in accordance with these statutory definitions, the

determination of whether a product may be regulated as a cosmetic, a drug, or both depends on the article's intended use.

1.2.2 The "Intended Use" Of A Product Is Determined Primarily By The Product's Labeling And Advertising

Congress, the courts, and FDA have all adopted the position that the "intended use" of a product is based primarily on the totality of the claims made for it. The legislative history of the Act shows that Congress understood that the manufacturer's representations in marketing a product would determine the product's intended use.

> "The use to which the product is to be put will determine the category into which it will fall . . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put." S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935).

The courts have treated this passage as authoritative. In *ASH v. Harris*, for example, the D.C. Circuit recognized that:

> "[T]he crux of FDA jurisdiction [lies] in *manufacturers' representations* as revelatory of their intent. . . . 'The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. . . .' Such an understanding has now been accepted as a matter of statutory interpretation."

655 F.2d 236, 238-39 (D.C. Cir. 1980)(quoting S. Rep. No. 361, *supra*, at 240). *See also United States v. An Article . . . "Sudden Change"*, 409 F.2d 734, 739 (2d Cir. 1969); *American Health Products v. Hayes*, 574 F. Supp. 1498, 1506 (S.D.N.Y. 1983), *aff'd per curiam*, 744 F.2d 912 (2d Cir. 1984); *United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951); 56 Fed. Reg. 60537, 60546 (November 27, 1991).

FDA's own longstanding regulations similarly recognize the decisive role that manufacturers' representations play in establishing intended use. According to the regulations:

> "The words *intended* uses or words of similar import . . . refer to the **objective intent** of the persons legally responsible for the labeling . . . [and such intent] is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. [emphasis added]

In the medical device context, FDA has reiterated that a manufacturer's marketing representations determine a product's "intended use":

> "FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the Agency will consider in determining the intended use of a particular product are the labeling,

advertising and other representations accompanying the product." 45 Fed. Reg. 60576, 60579 (September 12, 1980).

Labeling and advertising are ordinarily the controlling determinants of intended use. To the best of our knowledge, no court has ever held that a product was a drug in the absence of representations of therapeutic or physiological benefit made by the manufacturer or vendor in connection with its sale.

This is confirmed in a recent letter from FDA Chief Counsel Daniel E. Troy determining that an implanted identification device that has no medical purpose is not a medical device under the FD&C Act:

> "It is well settled that intended use is determined with reference to marketing claims.
>
> * * *
>
> . . . a foreseeable effect on the structure or function of the body does not establish an intended use.
>
> * * *
>
> Foreseeability by the manufacturer does not suffice to establish intended use. Rather, there must be 'objective intent' in the form of marketing claims."[6]

By preventing, removing, or reducing plaque accumulation, antiplaque products can lead to cleaner and whiter teeth, and fresher breath. The relevant statutory

---

[6] Letter from FDA Chief Counsel Daniel E. Troy to Jeffery N. Gibbs (October 17, 2002).

provisions and FDA regulations clearly dictate that, if a product – including an antiplaque product – is intended to be used solely for cosmetic purposes, based upon the claims made for it, it is subject to regulation as a cosmetic, and only as a cosmetic.

1.2.3 A Product Making A Qualified Antiplaque Claim Is A Cosmetic If The Intended Use Is For Cosmetic Purposes Only

1.2.3.1 FDA Recognizes That Oral Care Products, Including Mouthwashes And Dentifrices, Are Cosmetics And Not Drugs If They Are Intended To Be Used For Cosmetic Purposes Only

The FDA regulations identifying "cosmetic product categories" recognize that "dentifrices," "mouthwashes and breath fresheners," and "other oral hygiene products" may come within the definition of a cosmetic. 21 C.F.R. § 720.4(c)(9). Indeed, an oral hygiene product is ordinarily classified as a cosmetic if no therapeutic claims are made for it. For example, prior to the introduction of fluoride, all toothpastes in the United States were cosmetics and not drugs because they were sold solely for the purpose of cleaning (or whitening) teeth and freshening breath. Non-fluoride dentifrices continue to be regulated exclusively as cosmetics in the absence of disease claims. Similarly, FDA has classified mouthwashes as cosmetics for many years if they claim only to freshen breath and reduce malodor. FDA's OTC advisory panel on Oral Health Care Drugs affirmed that mouthwashes used for cleansing and deodorizing the mouth are cosmetics in the absence of therapeutic claims.[7/]

[7/] 47 Fed. Reg. 22760, 22778-79, 22,843-44

1.2.3.2 The Control Of Plaque Provides A Cosmetic Benefit

In its request for data on ingredients contained in antiplaque products, FDA commented that "[b]ecause plaque is a colorless bacterial layer which is not clearly visible unless calcified or stained, plaque removal is not considered a cosmetic purpose."[8] There are several problems with this statement. First of all, it repudiates clear statutory and regulatory language, consistently applied by the courts and FDA, which provides that a product's status as a drug or cosmetic depends on its *intended use*, which in turn is determined primarily by its labeling and advertising. If an antiplaque product making only cosmetic claims did not in fact fulfill these claims, it would be a misbranded cosmetic, not a drug.

Second, plaque removal has demonstrable cosmetic benefits. The Agency overstates plaque's "invisibility." After it reaches a certain thickness, supragingival plaque is readily detectible to the naked eye. It can impart a dull, dingy, or matted appearance to tooth surfaces.[9/] Moreover, although staining of the tooth enamel itself is relatively rare, plaque on the teeth commonly becomes stained by pigments from sources such as food and tobacco.[10/] Plaque can also become mineralized, forming unsightly deposits known as tartar.[11/]

---

[8] 55 Fed. Reg. at 38561.

[9/] E. Wilkins, *Clinical Practice of the Dental Hygienist* 241 (6th ed. 1989).

[10/] *Id.* at 254-57.

[11/] *Id.* at 249.

The FDA comment also overlooks the fact that a product does not have to have visual effects to qualify as a cosmetic. The list of cosmetic purposes in the statutory definition of "cosmetic" includes not only "altering the appearance," but also "cleansing, beautifying, [and] promoting attractiveness." 21 U.S.C. 321(i). The inclusion of "cleansing" leaves no doubt that an antiplaque product has a cosmetic purpose if it is used to promote "oral hygiene" or to "clean" or "freshen" the mouth or teeth.

The "cleansing" action of antiplaque products also has a tactile effect that is itself a cosmetic benefit. Plaque can be felt on the teeth as a "furry" or "dirty" coating that many people find unpleasant. Statements in the labeling of antiplaque products regarding "cleaner feeling teeth" or "smoother feeling teeth", for example, are valid cosmetic claims. FDA has long considered articles that change the feel of parts of the body, such as hair conditioners and creams, lotions, and moisturizers for the skin, to be cosmetics.[12]

The ability of antiplaque products to reduce bad breath, or halitosis, is clearly a cosmetic benefit, because the diminishment of unpleasant odors "beautifies" and "promotes attractiveness." It has frequently been held that the mitigation of odors is a cosmetic effect within the meaning of the Act. For example, advisory review panels have concluded that deodorant claims for mouthwashes[13/] and for vaginal douches and

---

[12] 21 C.F.R. §740.4(c)(5)(i); 21 C.F.R. §740.4(c)(12)(vi)

[13/] 47 Fed. Reg. at 22760, 22778-79, 22844.

suppositories[14/] are cosmetic claims, and FDA itself has reached the identical conclusion as to underarm deodorants[15/] and deodorant soaps.[16/] FDA regulations specifically classify mouthwashes and breath fresheners, underarm deodorants, and feminine hygiene deodorants as cosmetics.[17]

1.2.3.3 Antiplaque Representations Qualified By Reference To Cosmetic Benefits Are Cosmetic Claims, Not Drug Claims

Representations in labeling regarding the removal or reduction of plaque are often related, through qualifying statements, to the cosmetic outcomes discussed above. The majority of the Task Group takes the position, which is supported by the applicable statutory and regulatory language and by long practice, that plaque-related statements qualified by reference to cosmetic benefits are cosmetic claims exclusively.

The Subcommittee linked the **therapeutic** effects of antiplaque products with reduction of the disease gingivitis:

> "The Subcommittee accepts that gingivitis is associated with an accumulation of plaque along the gingival margin but is unaware of any evidence that shows that there is a close correlation between the amount of plaque and the induction of gingivitis, as can be assessed using

---

[14/] 48 Fed. Reg. at 46684, 46701.

[15/] 47 Fed. Reg. at 36492, 36494; 43 Fed. Reg. at 46694, 46712.

[16/] 56 Fed. Reg. at 33648-49.

present day methods. It should be noted that the relationship between the quantity of plaque present and the degree of gingivitis is sufficiently complex such that reductions in plaque mass alone are inadequate to conclude that a therapeutic effect on gingivitis could be expected. Therefore, gingivitis reductions must be measured directly."[18]

An antiplaque claim is not inexorably a drug claim, however, because plaque itself may not have an effect on the disease, gingivitis. Plaque is, rather, a phenomenon that occurs universally in even the healthiest individuals and has both disease-related and cosmetic consequences. Plaque buildup can lead to the development of gingivitis and periodontal disease, but as indicated by the above quotation from the Subcommittee, it does not invariably do so. On the contrary, "mouths can frequently be observed in which plaque is not associated with disease."[19/] Scientific studies reviewed by the Subcommittee have provided evidence that some types of plaque are not related to gingivitis and other forms of gum disease at all.[20/]

---

[17] 21 C.F.R. § 720.4I(9)(ii), (10)(ii), (10)(iv).

[18] 68 Fed Reg at 32237.

[19/] Bowen, *The Prevention or Control of Dental Plaque*, in *Dental Plaque* 283 (W. McHugh ed. 1970). *See also* Bowen, *Future Directions for Dental Plaque Control Measures and Oral Hygiene Practices: Perspective II*, in *Dental Plaque Control Measures and Oral Hygiene Practices* 306 (H. Löe & D. Kleinman, ed. 1986)("[T]here is no simple, direct relationship between the accumulation of dental plaque and the onset of oral disease."); Ramfjord et al., *Oral Hygiene and Maintenance of Periodontal Support*, 53 J. Periodontal 26 ("In many children and some adults one may find definite plaque on the teeth without clinical evidence of gingivitis.").

[20/] M. Pader, *Oral Hygiene Products and Practice* 69 (1988) and 68 Fed Reg at 32236.

The undeniable cosmetic consequences of plaque and the strong cosmetic associations of plaque removal products would make it unreasonable for FDA to conclude that a claim of plaque removal can *only* be a disease prevention indication. The cosmetic or drug status of an antiplaque product must be determined primarily by qualifications of the antiplaque claim as reflected in the totality of the product's labeling and advertising.