C·T·F·A
Representing the personal care products industry

November 8, 1993

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President

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Hormone Substances Used As
Ingredients In Cosmetic Products
Docket No. 91N-0245
58 Fed. Reg. 47611 (September 9, 1993)

The Cosmetic, Toiletry, and Fragrance Association (CTFA), founded in 1894, has more than 240 members who manufacture and distribute health and beauty aids. These companies market the vast majority of finished cosmetic products sold in the United States. CTFA also represents more than 250 suppliers of goods and services to the personal care product industry.

Because the regulation of cosmetic products is an issue of paramount importance to its members, CTFA submits these comments in response to the FDA proposed regulation on hormone substances used as ingredients in cosmetic products. CTFA opposes the novel suggestion -- never before advanced by FDA in any court or in any regulatory proceeding -- that the use of an ingredient which in any way affects the structure or function of the body inherently converts a consumer product from a cosmetic to a drug even if only cosmetic claims and representations are made for the product. CTFA opposes any suggestion that cosmetic products can be made subject to regulation as drugs solely on the basis of the ingredients used, absent any drug claims.

I. Natural and Synthetic Hormones Can Serve Valid and Appropriate Cosmetic Functions.

Natural and synthetic hormones (including steroid products which, although not hormones, are classified as hormone ingredients for purposes of FDA regulation) can perform valid and appropriate cosmetic functions in cosmetic products, unrelated to the drug functions for which FDA promulgated 21 C.F.R. § 310.530 in 58 Fed. Reg. 47608 (September 9, 1993). Natural and synthetic hormones may act as humectants. They may act as cosmetic moisturizers, helping to keep water in the skin and thus to plump and firm the skin. They are classic cosmetic ingredients in classic cosmetic products. FDA has never suggested that moisturizer ingredients or moisturizer products are drugs, and the only court

91N-0245

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C1

that has addressed this matter has agreed that they are cosmetics. United States v. An Article . . . Sudden Change, 409 F.2d 734, 741 n.10 (2d Cir. 1969).

Natural and synthetic hormones may also have other functional cosmetic purposes in addition to their moisturizing capacity. Like many cosmetic ingredients, in an appropriate formulation they might provide the right texture and tactile aesthetic that is so essential to consumer acceptance of cosmetic products. These functions bear no relationship to the drug functions covered by the recently-promulgated 21 C.F.R. § 310.530.

FDA has, in fact, recognized that hormone ingredients have valid and appropriate cosmetic functions in cosmetic products. The proposed regulation explicitly recognizes that the functions performed by pregnenolone acetate and progesterone in cosmetic products are solely cosmetic functions and are not drug functions. The functions of other natural and synthetic hormone ingredients in cosmetic products are indistinguishable from the functions of pregnenolone acetate and progesterone. FDA contends that these other hormone ingredients "do not have any legitimate cosmetic uses," but the agency offers no data or information for this novel and unsupportable assertion. Without supporting evidence in the administrative record, this contention cannot stand.

II. Presently Marketed Cosmetic Products Appear to Use Primarily Pregnenolone Acetate and Progesterone at Relatively Low Levels.

CTFA has made no attempt to conduct an independent survey of the use of natural and synthetic hormone ingredients in cosmetic products. The Association is aware that both natural and synthetic hormone ingredients are currently used in marketed products and have been so used for decades. Neither CTFA nor members of the Association are aware of any adverse consequences from this use.

At present, the principal hormone ingredients used in cosmetic products are pregnenolone acetate and progesterone. They are used at low levels, below the amounts discussed by FDA in the preamble and the proposed regulation. To the extent that natural hormone ingredients are used, they are also present in very low levels.

III. Natural and Synthetic Hormone Ingredients Serve Valid and Appropriate Cosmetic Functions Regardless Whether They Also Incidentally Have Some Effect on the Structure or Function of the Body.

Scientists have long understood that many things that touch the human body may in some way affect the structure or function of that body. This includes air, water, cosmetics, food, and other forms of consumer products (e.g., detergents, pesticides, and so forth). Even a very small amount of contact may have some effect, whether or not it can be seen, felt, or measured.

The difference between a drug on the one hand, and other forms of consumer products, relates to the intended purpose of the product, not whether the product in fact in some way affects the structure or function of the body. A drug is intended to affect a bodily function. A food is intended to nourish, a cosmetic is intended to beautify, a detergent is intended to wash objects, and other consumer products are intended to serve their specific functions, even though they may in fact unintentionally affect the structure or function of the body.

Cosmetic ingredients are incorporated in cosmetic products at levels that serve a valid and appropriate cosmetic function, regardless of whether they may also affect the structure or function of the body at those levels. The intended use of all of these ingredients, however, is to beautify, not to have some therapeutic or related drug effect.

IV. The Distinction Between a Cosmetic and a Drug Depends Upon the Claims or Representations Made for the Product, Not on the Inherent Characteristics of the Product.

The definitional difference between a cosmetic and a drug under Sections 201(g) and (i) of the FD&C Act rest upon the "intended" use of the article. The legislative history makes clear that it is the "representations" that are made for the article that will determine the proper regulatory classification:

> "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). In cases in which the distinction between a cosmetic and a drug was in contention, the courts have uniformly looked to the labeling and advertising of a product to determine the "intended" use. United States v. An Article . . . Sudden Change, 409 F.2d 734, 739-742 (2d Cir. 1969); United States v. An Article . . . "Line Away", 415 F.2d 369, 371-372 (3rd Cir.). In National Nutritional Foods Association v. Mathews, 557 F.2d 325, 333-336 (2d Cir. 1977), the court held that FDA could not subject dietary supplements containing high levels of vitamin A and D to regulation as drugs, merely because those high levels have a "drug" effect, unless it could also identify labeling claims or other evidence to show that these products were "intended" to function as drugs. Similarly, in Action on Smoking & Health (ASH) v. FDA, 655 F.2d 236, 239-241 (D.C. Cir. 1980), the court held that cigarettes were not drugs simply because they affect the structure or function of the body, unless there was evidence that the products were "intended" to be used for this purpose.

FDA has, until now, uniformly followed this approach in distinguishing between a cosmetic and a drug. In defining "intended uses" in 21 C.F.R. § 201.128, for example, FDA has stated that "intended use" refers:

> ". . . to the objective intent of the persons legally responsible for the labeling of drugs. The 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. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised."

At no point in this regulation does FDA state that the "intended use" may be shown by the intrinsic nature of the article itself or the level at which an ingredient is included. Rather, objective intent is shown by the claims and representations.

This is consistent with the position that FDA has taken throughout the Over-the-Counter (OTC) Drug Review. For example, in discussing the regulation of debriding agents in the tentative final monograph (TFM) for nonprescription oral health care drug products, FDA stated that ingredients recognized in an OTC drug monograph need not comply with the terms of the monograph if only cosmetic claims are made for the product. 53 Fed. Reg. 2436, 2446 (January 27, 1988) ("Products marketed only as cosmetics are not subject to this rulemaking."). Similar statements by FDA may be found in a number of other tentative final monographs, e.g., 48 Fed. Reg. 6820, 6822 (February 15, 1983) (skin protectants) and 47 Fed. Reg. 39108, 39114 (September 3, 1982) (skin bleaching agents).

Furthermore, in recognizing the CTFA Cosmetic Ingredient Dictionary, FDA stated that the mere reference to "placental extract" on the labeling of a cosmetic would not necessarily classify the product as a drug, absent a drug claim. 45 Fed. Reg. 3574, 3576 (January 18, 1990).

It is apparent that, in the course of the present rulemaking, FDA has totally reversed its long-held approach to the matter. When the agency published its TFM for topically-applied hormone-containing OTC drug products, it concluded that, absent a drug claim, all natural and synthetic hormone ingredients could properly be included in a cosmetic product, at <u>any</u> level:

> "A product that contains hormone ingredients can be either a cosmetic or a drug, or both, depending on the intended use of the product. If the skin care products that contain estrogen, progesterone, and pregnenolone acetate, which are currently subject to new drug applications, were to be relabeled as discussed above (i.e., no reference to the term 'hormone'), the products could properly be regulated as cosmetics alone."

54 Fed. Reg. 40618, 40620 (October 2, 1989). This preamble went on to state that:

> "Skin care products that contain hormones are solely cosmetics if the claims and the labeling, promotional material, advertising, and other relevant materials are only cosmetic in nature (e.g., to promote attractiveness), and no actual or implied therapeutic claims, or claims that the product will effect the structure or function of the body are made."

The agency's statements in the October 1989 proposal are consistent with the legislative history, administrative interpretation, and judicial construction of the FD&C Act, and are completely inconsistent with the September 1993 tentative final order.

Inclusion of a natural or synthetic hormone at a particular level is not a representation or claim of drug utility. Where a product is specifically labeled only to promote attractiveness, and no drug-type claim (not even use of the word "hormone") is made in labeling or advertising, there is no basis whatever for determining that the product is a drug.

V. FDA Has Full Legal Authority to Prohibit, Either by Court Action or Through Rulemaking, Any Cosmetic Ingredient that is Unsafe.

CTFA is unaware that natural or synthetic ingredients are unsafe at the levels at which they are currently used. Where FDA has evidence that a cosmetic ingredient is unsafe at any level, or at particular levels, it has unquestioned authority to prohibit that unsafe use either by initiating judicial proceedings or through rulemaking. Examples where FDA has prohibited ingredients in cosmetics on the basis of specific identified safety concerns are listed in regulations in 21 C.F.R. Part 700: bithionol, mercury, vinyl chloride, halogenated salicylanilides, zirconium, chloroform, and methylene chloride. In the present case, however, the agency has failed to identify in the administrative record any specific safety concerns sufficient to support a regulation of this type.

VI. The Ingredient Names for Natural and Synthetic Hormones.

FDA proposes to establish ingredient names under 21 C.F.R. § 701.30 for two synthetic ingredients: pregnenolone acetate and progesterone. The preamble to the proposed regulation, however, does not fully state the way in which cosmetic ingredient names are designated.

Under Section 701.3(c), a cosmetic ingredient shall be identified in the declaration of ingredients by the name specified by the Commissioner in Section 701.30, or in the absence of that the name in the CTFA Cosmetic Ingredient Dictionary, or in the absence of that the USP, the FCC, and the USAN and USP Dictionary of Drug Names. None of the natural or synthetic hormones are listed in the second edition of the CTFA Cosmetic Ingredient Dictionary (1977), the version currently recognized in Section 701.3(c)(2). Pregnenolone acetate is listed in the third edition (1982), which FDA has stated may properly be used for purposes of cosmetic ingredient labeling.

CTFA has no objection to the two names listed. The CTFA Cosmetic Ingredient Dictionary will be amended from time to time to include other natural and synthetic hormones if it is concluded that this action is appropriate for cosmetic products.

VII. Conclusion

FDA has proposed action that is without factual or legal basis. FDA proposes to prohibit the use of hormone ingredients in cosmetic products simply because those ingredients are contained in a cosmetic product at or above a certain level. The agency makes this proposal claiming that those ingredients at those levels would affect the structure or function of the body without regard for evidence as to whether this is the manufacturer's intent or not. This action flies in the face of the Food, Drug, and Cosmetic Act and FDA's long-standing interpretation of that law. FDA offers no rationale for this departure from the law in its treatment of hormone ingredients. Moreover, there simply is no evidence to justify FDA's action with respect to these ingredients based either on drug effect or safety. We urge the agency to modify its proposed regulation to be consistent with the long-standing distinction between drugs and cosmetics based on evidence of the manufacturer's intended use of the product.

Respectfully submitted,

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