C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

September 2, 2003

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

E. EDWARD KAVANAUGH
PRESIDENT

Re: Skin Protectant Drug Products for Over-the-Counter Human Use: Final Monograph; Docket Nos. 78N-0021 and 78N-021P – Request for Off-Label Disclosure of Inactive Ingredients

Dear Sir or Madam:

These comments are filed on behalf of The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA")[1] with respect to the Final Monograph for Skin Protectant Drug Products. 68 Fed. Reg. 33362 (June 4, 2003) In that publication, FDA has provided for public comment on the portions of the regulation that provide for reduced labeling to comply with FDA's OTC Drug Labeling Regulation for certain skin protectant products.

CTFA supports the Agency's action to provide greater flexibility for certain skin protectant products to comply with the "Drug Facts" labeling requirements of the OTC Drug Labeling Regulation. We have noted in many other contexts that a "one size fits all" labeling scheme is neither necessary nor practical for all OTC drugs, especially cosmetic-drugs. While the relief granted is more limited than we believe is justified, FDA has correctly recognized that two factors – small packaging and the inherently safe nature of the products – each provide a basis for allowing greater flexibility for labeling,

78N-021P C5

[1] CTFA is the national trade association founded in 1894 to represent the personal care products industry. CTFA has almost 600 members. Approximately one-half, active members, manufacture and distribute the vast majority of these products sold in the United States. The other one-half of CTFA's members, associate members, provide goods and services to those active members. Many traditional cosmetic products are now sold as both drugs and cosmetics, providing dual benefits to consumers. Such products frequently provide skin protectant, sunscreen and other drug benefits in combination with cosmetic benefits.

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702
202.331.1770 FAX 202.331.1969
http://www.ctfa.org

The Final Monograph for Skin Protectants allows reduced labeling for certain lip protectants, products containing only cocoa butter, petrolatum, or white petrolatum, used singly or in combination and marketed other than as a lip protectant; and for certain sunscreen drug products labeled for use only on specific small areas of the face (e.g. lips, nose, ears, and/or around eyes). Similar relief was provided in the Sunscreen Monograph for lipsticks and sunscreens labeled for use only on specific small areas of the face.[2]

In allowing reduced labeling, the agency recognized that products covered by this monograph meet certain criteria also recognized in the Sunscreen Monograph: they are typically packaged in small amounts, are applied to limited areas of the body, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warning. 68 Fed. Reg. 33362, 33371.

We are filing these comments to urge FDA to consider a greater degree of flexibility for skin protectants and skin protectant/sunscreen combination products – the ability to provide information on inactive ingredients off-label at the point of sale. Certain categories of OTC Drugs that are often marketed to provide both cosmetic and OTC drug benefits are not appropriate products for mandatory use of full "Drug Facts" labeling. Skin protectants, sunscreens and skin protectant/sunscreen combination products are among those categories.

This modification of the OTC drug labeling requirements is both appropriate and necessary for products such as lip balms and lip balms with sunscreen which are sold in very small containers similar to those used to dispense lipsticks containing sunscreens. Additional flexibility also is appropriate for all products that meet the Agency's criteria listed above. Therefore, we urge the agency to allow greater flexibility for labeling such products whether they are categorized as skin protectants, sunscreens or skin protectant/sunscreen combination products.

This relief – off-label listing of inactive ingredients – was requested in our October 6, 1997 comments on the OTC Drug Labeling Regulation and our comments of August 4, 2000 that specifically addressed sunscreen drug products.[3] Labeling issues for sunscreens are still under active consideration and amendments to the Final Monograph for Sunscreens are expected to be published later this year. We are filing this comment on the Skin Protectant

---

[2] 21 C.F.R. Section 352.52; Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999).
[3] CTFA Comment of August 4, 2000 at 23-24; Docket 78N-0038

Monograph because we believe the requested relief is necessary as well for certain skin protectant and skin protectant/sunscreen combination products.

The action requested is to permit the often extensive inactive ingredient information to be included in labeling "accompanying the product" if the package has a total surface area of less than 12 square inches and is not enclosed in an outer container, criteria established for off-label disclosure for certain cosmetic products.[4]

FDA has expressed a concern that it does not have legal authority to allow off-label disclosure of inactive ingredients for OTC drug products. As we have argued in comments to the sunscreen rulemaking docket, we believe FDA does have that authority and do not believe it was changed by the FDA Modernization Act (FDAMA) requirements for labeling of inactive ingredients for OTC drugs.

Section 412 of the FDA Modernization Act amended the misbranding provisions of the Food, Drug, and Cosmetic Act to state that an OTC drug will be misbranded unless its label bears, among other things, "the established name of each inactive ingredient listed in alphabetical order on the outside container of the package...." FD&C Act Section 502(1)(iii) This provision was incorporated into the final rule establishing a standard format for the labeling of such products. 64 Fed. Reg. 13254 (1999)

However, Section 502 as amended by FDAMA, did not alter the misbranding provision of the law that states "to the extent that compliance with the requirements of subclause...(iii)...is impractical, exemptions shall be established by regulations promulgated by the Secretary." Thus, it is clear that FDA retains the authority to grant relief from the inactive ingredient listing requirements in appropriate circumstances. In addition, consumers will be protected because there is a time-tested, proven labeling alternative currently in use for cosmetics which allows those same types of ingredients to be disclosed off-label at the point of sale. We urge FDA to make use of this authority to provide a more feasible mechanism for manufacturers to comply with ingredient listing requirements for certain products and packages.

We urge the Agency to allow this additional labeling flexibility in these limited circumstances. This greater flexibility will benefit the consumer by allowing products which FDA recognizes to be highly-beneficial and safe to be available to the consumer in convenient, easy-to-use packaging.

---

[4] See 21 C.F.R. Sec. 701.3(i)

Please feel free to contact us if you have questions or need further information.

Respectfully submitted,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel

cc: Charles J. Ganley, M.D. (HFD-560)
Gerald M. Rachanow, Esq. (HFD-560)