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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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E. EDWARD KAVANAUGH
PRESIDENT

August 22, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20857

CITIZEN PETITION: DOCKET 78N-0038

Dear Sir or Madam:

This Citizen Petition is submitted under 21 CFR Sec. 10.30 on behalf of The Cosmetic, Toiletry, and Fragrance Association[1] and The Consumer Healthcare Products Association[2] ("Petitioner"). This Citizen Petition requests the Commissioner of Food and Drugs to take the following action with respect to the Final Monograph for Over-the-Counter Sunscreen Drug Products, 21 CFR Part 352, Subpart C (Final Monograph).

ACTION REQUESTED

The Petitioner requests the Commissioner to reopen the administrative record of the Final Monograph for the purpose of considering the attached information when developing the proposed amendments to the final monograph.

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[1] CTFA is the national trade association representing the personal care products industry. It has an active membership of almost 600 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States, as well as a large number of OTC drug products and products that are both drugs and cosmetics. CTFA also includes associate member companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories.
[2] CHPA is the national trade association representing the manufacturers and distributors of nonprescription or over-the-counter (OTC) medications. Members of CHPA are responsible for over 90 percent of the retail sales of OTC drugs in the United States. In addition, CHPA members manufacture and distribute some products that are both drugs and cosmetics.

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

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STATEMENT OF GROUNDS

The agency's regulations recognize that the administrative record of a final monograph may be reopened to consider new data and information, see 21 CFR 330.10 (a)(12)(i), and that the Commissioner may publish a proposed amendment if the Commissioner finds general recognition of safety, effectiveness and labeling under 21 CFR 330.10 (a)(4). In fact, FDA has already indicated its intention to do so in this rulemaking.[3]

On May 21, 1999 FDA published a final rule for OTC sunscreen drug products in Part 352 intended to provide UVB radiation protection, however, the final monograph did not address active ingredients, labeling, and test methods for products intended to provide UVA protection. In addition, CTFA and CHPA petitioned FDA to reconsider a number of decisions regarding SPF claims, anti-aging claims, uses and directions, and labeling to be required under the OTC Drug Labeling Regulation. Accordingly in the Federal Register of June 8, 2000 FDA extended the effective date for all OTC sunscreen drug products in order for the agency to develop a comprehensive sunscreen final monograph that addresses the formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352.

Petitioner filed extensive comments on specific information the agency requested when it reopened the administrative record in the June 8 notice. As part of our September 2000 submission, we urged FDA to include additional indications for sunscreen products. The attached document provides further scientific rationale for inclusion of the claim "Helps protect against skin aging caused by the sun" in the Final Monograph for Sunscreen drug products.

Three additional years have now passed, and we feel it is essential that FDA base its decisions on the most current information with respect to anti-aging claims to be permitted. The purpose of this petition is to provide updated scientific literature, and to enable the Agency to decide this issue with all the evidence before it. The information included in the attached materials is directly relevant and essential for the agency to consider in drafting its proposed amendment to the Final Monograph. In particular, it would be inappropriate for FDA to restrict or ban information about the benefits of sunscreens in reducing the effects of the sun without consideration of current scientific information. We are asking the Agency to consider this material as providing new support for actions requested of FDA.

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[3] 66 Fed. Reg. 67485 (December 31, 2001)

In sum, the attached material is directly relevant to the proposed conditions under which sunscreen products may be marketed. Good cause exists for the Commissioner to consider this material because it provides further scientific data and rationale for the need to expand the indications for sunscreen products, at a time when the Agency has raised such questions.

ENVIRONMENTAL IMPACT

According to 21 CFR 25.31(c), this petition qualifies for a categorical exclusion from the requirement that an environmental assessment be submitted.

ECONOMIC IMPACT

According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this petition.

CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data know to the Petitioner which are unfavorable to the petition.

Respectfully submitted,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

Eve E. Bachrach
Senior Vice President, General Counsel and Secretary
Consumer Healthcare Products Association

cc: Charles J. Ganley, M.D. (HFD-560)
Matthew R. Holman (HFD-560)

Attachment