

Memorandum of Meeting
Docket No. 78N-0038

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Attendees

E. Edward Kavanaugh (CTFA)
Thomas J. Donegan, Jr. (CTFA)
John Roberts (Hogan & Hartson)
Charles Ganley (CDER)
Daniel Troy (OCC)
Ann Wion (OCC)
Eric Blumberg (OCC)
Erica Keys (OCC)
William McConagha (OCC)

Discussion

On October 29, 2001, agency officials met with representatives of the Cosmetic, Toiletry, and Fragrance Association (CTFA) to discuss CTFA's numerous submissions to Docket No. 78N-0038 regarding labeling requirements for over-the-counter (OTC) sunscreen drug products. The discussion focused on (1) the labeling requirements set forth in the Sunscreen Final Monograph (21 C.F.R. 352.52); and (2) the application of the OTC "Drug Facts" labeling requirements (21 C.F.R. 201.66) to cosmetic products that contain sunscreen ingredients.

The representatives of CTFA made the following specific requests:

- 1) Elimination of any limit on SPF claims (currently at 30+).
- 2) Elimination of restrictions on anti-aging claims for sunscreens.
- 3) Provide a broader and more appropriate selection of approved uses and directions to fit the wide variety of sunscreen products on the market.
- 4) Allow reduced labeling under the OTC Labeling Regulations for all sunscreens, skin protectants and antiperspirants. Allow combination cosmetic-sunscreen products to disclose inactive ingredients off-label at the point of sale.

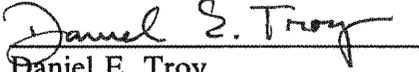
In support of their requests, the representatives from CTFA cited recent First Amendment jurisprudence and a number of policy concerns.

The agency stated that it will give serious consideration to each of the issues raised during the discussion as it prepares proposed amendments to the sunscreen final monograph (See 65 FR 36319, June 8, 2000, re-opening the administrative record for the sunscreen monograph to allow for publication of a revised, comprehensive monograph). The agency also stated that it

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intends to further delay the effective date for the Sunscreen Final Monograph, and hopes to formally publish that delay in the Federal Register by the end of December.


Daniel E. Troy
Chief Counsel
Food and Drug Administration