DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administrati
.. Rockville MD 20857

JUN 3 2003

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, N.W., Suite 300
Washington, D.C. 20036-4702

Re: Docket No. 78N-0038
Comment No. PSA3

Dear Mr. Donegan:

This letter is in response to your petition for stay of action and reconsideration of effective date, submitted on July 26, 2002, on behalf of the Cosmetic, Toiletry, and Fragrance Association (CTFA) and the Consumer Healthcare Products Association (CHPA).

I. PETITIONER'S REQUEST AND FDA'S DECISION

You requested reconsideration and stay of the effective date of a technical amendment to the final monograph for sunscreen drug products for over-the-counter (OTC) human use in 21 CFR part 352. The technical amendment to part 352 was published in the *Federal Register* of June 20, 2002 (67 FR 41821) (technical amendment). You specifically requested that the Food and Drug Administration (FDA) immediately stay the effective date for four sunscreen ingredient name changes that appeared in the technical amendment and publish an amended regulation giving manufacturers an additional year, until September 1, 2003, to incorporate these ingredient name changes on product labels. As an alternative, you requested that FDA provide notice to the industry that the Agency will exercise enforcement discretion for affected products until September 1, 2003

The Agency has reviewed your petition and denies your request for a stay of the effective date of the technical amendment. The basis for this decision is set forth below. We have granted your alternative request for notice by issuing the enclosed guidance regarding our exercise of enforcement discretion concerning these name changes.

II. DISCUSSION

A. Established Names

As discussed in the June 20, 2002, technical amendment, the Federal Food, Drug, and Cosmetic Act (the Act) requires the label of a drug to bear the drug's established name (section 502(e)(1)(A)(i) of the Act (21 U.S.C. 352(e)(1)(A)(i)). In section 502(e)(3) of the Act, the established name of the drug is defined as

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> (A) the applicable official name designated pursuant to section 508 [of the Act], or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient . . . .

Section 508 of the Act (21 U.S.C. 358(a)) authorizes FDA to designate an official name for any drug if FDA determines "that such action is necessary or desirable in the interest of usefulness and simplicity." FDA does not, however, routinely designate official names for drug products under section 508 of the Act. In the absence of designation by FDA of an official name, interested persons may rely on the current compendial name as the established name (*See* 21 CFR 299.4(e).

FDA has not designated official names for the following active ingredients: menthyl anthranilate, octyl methoxycinnamate, octyl salicylate, and phenylbenzimidazole sulfonic acid. The current compendial names established by the United States Pharmacopeia (USP) are: meradimate for methyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. USP has determined that these compendial names are effective September 1, 2002 Therefore, in accordance with the naming process set forth in section 502(e) of the Act, the established names for these ingredients are the USP compendial names, which are effective on September 1, 2002. Manufacturers are required to relabel their products as a result of the USP name changes to remain in compliance with section 502(e) of the Act.

B. Request for Stay of the Technical Amendment

You requested that FDA stay the effective date of the technical amendment in accordance with 21 CFR 10.35. Section 10.35 provides in part:

> (a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.
>
> (b) An interested person may request the Commissioner to stay the effective date of any administrative action. . . .

The Agency denies your request for a stay because FDA has not yet established an effective date for the technical amendment; the effective date in the June 20, 2002 *Federal Register* notice was issued in error and will not be incorporated into the *Code of Federal Regulations* (CFR) at this time. As discussed in the preamble to the technical amendment, the technical amendment was intended to make the monograph consistent with the USP name changes before the compendial names became effective on September 1, 2002. The technical amendment was also intended to

remind manufacturers of the USP effective date. FDA now realizes, however, that the Agency is unable to revise the established names listed in § 352.10 until the indefinite stay for part 352 (published in the *Federal Register* of December 31, 2001, 66 FR 67485) is lifted. Part 352 will remain stayed until FDA has issued a comprehensive sunscreen final monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352, or until further notice. Accordingly, the technical amendment, though published in the *Federal Register* on June 20, 2002, is not yet effective and will not be incorporated into the CFR until the comprehensive final monograph is issued.[1] Therefore, your request for a stay of the technical amendment is denied because there is no "effective date" upon which to grant a stay of action under § 10.35(a) or (b).

The technical amendment, however, has no impact on the statutory requirement to comply with the naming process set forth in section 502(e) of the Act. Manufacturers are required to update their labeling as a result of the Act, not the technical amendment. Thus, because the established name is a statutory requirement, FDA's actions regarding the technical amendment do not relieve manufacturers from their obligation to comply with the Act.

C. Enforcement Discretion

As an alternative to your request for a stay, you requested that FDA provide notice that it will exercise enforcement discretion and not require these name changes to appear on all sunscreen product labels introduced into interstate commerce before September 1, 2003.

In support of your request, you assert that FDA's publication of the technical amendment on June 20, 2002, has given sunscreen manufacturers using these four active ingredients little more than 60 days to make changes to their product labels. In addition, you state that there was uncertainty over the timing of FDA's action to implement the USP name changes in the context of its announced intent to publish a proposed amendment to the sunscreen monograph that will require additional labeling changes. You state that a delay of 1 year, until September 1, 2003, will provide the opportunity for sunscreen manufacturers to deplete their existing label inventory and comply with the technical amendment. Finally, you assert that failure to extend the deadline for relabeling will unnecessarily disrupt the supply of sunscreen products, and there is no reason to disrupt this supply to implement a technical labeling change that will not in any way adversely affect the safety of consumers or the ability of consumers to obtain effective sunscreen protection.

The Agency agrees that the time from publication of the technical amendment on June 20, 2002 to the September 1, 2002 effective date was a relatively short period. Moreover, we agree that

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[1] An effective date note has now been added to 21 CFR part 352, providing:

> [a]t 67 FR 41823, June 20, 2002, § 352.20 was amended by revising paragraphs (a)(1) through (a)(2), effective Sept. 1, 2002. This amendment could not be incorporated because at 66 FR 67485, Dec. 31, 2001 the effective date was stayed until further notice.

industry could have experienced some uncertainty regarding the Agency's timing for implementation of the USP name changes. The sunscreen final monograph that published on May 21, 1999, had an initial effective date of May 21, 2001. That date was extended to December 31, 2002, in the *Federal Register* of June 8, 2000 (65 FR 36319), and was subsequently stayed until further notice in the *Federal Register* of December 31, 2001. In the December 2001 notice, the Agency stated that it anticipates that the new effective date will not be before January 1, 2005. The Unified Agenda, published on May 13, 2002, listed several future publications for sunscreen products: Final Action (Names) 07/00/02 and NPRM (UVA/UVB) 04/00/03. As you noted, the Agency's revision of the sunscreen final monograph to change the ingredient names (technical amendment) was published on June 20, 2002. The Agency agrees that these various dates could have caused confusion for some manufacturers of OTC sunscreen drug and drug-cosmetic products.

For these reasons, we agree that it would be reasonable to provide sunscreen manufacturers an additional year to deplete their existing label inventory and comply with the statutory obligation to bear the new established names Accordingly, the Agency has issued guidance regarding its intent to exercise enforcement discretion for sunscreen drug products that do not bear the new established names. This guidance is enclosed.

III. COMMENTS

Any comment that you wish to make on the above information should be submitted in triplicate, identified with the docket and comment numbers shown at the beginning of this letter, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

William K. Hubbard
Associate Commissioner
for Policy and Planning

Enclosure