DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 16 2003

Robert M. Sayre, Ph.D.
8621 Loxley Fairway
Cordova, Tennessee 38018

Ramon Fusaro, M.D., Ph.D.
984360 Nebraska Medical Center
Omaha, Nebraska 68198-4360

Re: Docket No. 03P-0067
Comment No. CP1

Dear Drs. Sayre and Fusaro:

This letter represents FDA's response to your citizen petition (CP1) submitted on February 13, 2003 and received on February 26, 2003. Your petition requested the Food and Drug Administration (FDA) to amend 21 CFR Part 352 (the monograph for sunscreen drug products for over-the-counter (OTC) human use; hereafter referred to as the OTC Sunscreen Monograph) to "establish product labeling and provide tests for products intended for recommendation by physicians for the particular needs of dermatological patients."

I. PETITIONER'S REQUEST AND FDA'S DECISION

You request that FDA establish a prescription product category for sunscreen drug products whose labeling is directed at physicians. You identify a number of clinical conditions suitable for physician labeling, e.g., melanoma, non-melanoma skin cancer, actinic keratoses, lupus erythematosus, polymorphous light eruptions, and drug photosensitivity. You contend that there are no prescription sunscreens and that "there is no provision for either testing or labeling a sunscreen product for any dermatological condition or clinical need." You highlight the need for such testing and labeling by pointing out that the action spectra and response spectra for dermatological conditions differ from the erythema spectra of "normal" subjects used to test sunscreen drug products under the OTC Sunscreen Monograph.

FDA has reviewed your petition and denies your request. The basis for this decision is set forth below.

II. DISCUSSION

You state that "there is no provision for either testing or labeling a sunscreen product for any dermatological condition or clinical need." This statement is incorrect because a sunscreen drug product could be marketed as a prescription drug product for the desired indications after FDA approval of a New Drug Application (NDA). In addition, an interested party could submit data in a citizen petition under 21 CFR 10.30 to establish professional labeling in the

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OTC Sunscreen Monograph. Professional labeling does not appear in OTC drug product labeling but is provided to health professionals. Three potential routes to gain FDA approval for requested labeling and testing are described below.

A. Prescription Sunscreen Drug Products

Any interested party can submit an NDA for a prescription sunscreen drug product for any dermatological or other condition requiring protection from solar radiation. An NDA submitted with labeling that is directed at physicians, as described in your petition, would be classified as a prescription drug product. FDA will approve the NDA if it contains adequate data to demonstrate the safety and efficacy of the sunscreen for the requested indication(s).

B. OTC Sunscreen Drug Products

1. NDA

This mechanism is not an appropriate route to market a sunscreen drug product as described in your petition. OTC drug products marketed under approved NDAs are labeled for consumers and do not require the direct supervision of a healthcare professional. The agency would have to evaluate the safety and effectiveness data submitted and determine whether any of the clinical conditions you mentioned in your petition would be appropriate to include in OTC sunscreen product labeling.

2. OTC Drug Monograph

As you indicated in your petition, the OTC Drug Review does not cover prescription drug products. However, under the OTC Drug Review, professional labeling has been included in the monographs for certain OTC drug products:

- antacids (§ 331.80)
- antiflatulents (§ 332.31)
- topical antifungals (§ 333.280)
- antiemetics (§ 336.80)
- antihistamines, antitussives, bronchodilators, expectorants, and nasal decongestants (§ 341.90)
- internal analgesics (§ 343.80)
- ophthalmic demulcents (§ 349.80)
- anticaries fluoride treatment rinses (§ 355.60)
- anthelmintics (§ 357.180)
- cholecystokinetics (§ 357.280)

These regulations specify that the professional labeling is to be provided to healthcare professionals and not to the general public. Thus, professional labeling for OTC sunscreen drug products could be added to the OTC Sunscreen Monograph.

With regard to your petition, professional labeling could be used to direct physicians to inform patients with certain clinical conditions to use high SPF sunscreens with UVA protection. However, in order to establish professional labeling for OTC sunscreen drug products, you or other interested parties must submit the appropriate safety and efficacy data to support the "professional" indication(s). This means that the specific active ingredient(s) must be studied in the appropriate population (e.g., consumers with lupus erythematosus). Your petition did not contain this information. Likewise, if new testing methods or modifications to the existing testing procedures are needed, interested parties should present that information to the agency. We suggest that interested parties present protocols for identifying the study population(s), developing the testing procedures, and developing appropriate labeling for agency comment. Data and supporting information can be presented to the agency in a petition to amend the OTC Sunscreen Monograph in the same manner as you submitted this petition.

III. CONCLUSION

Your request can be done in several ways. First, any interested party can submit an NDA for a prescription sunscreen drug product. Second, any interested party can submit a citizen petition requesting that FDA amend 21 CFR Part 352 to establish professional labeling for OTC sunscreen drug products. In both cases, the appropriate safety and effectiveness data and the necessary testing methods, which your petition did not include, would have to be submitted.

For the reasons stated above, the agency denies your petition. 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,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE:

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 03P-0067-CP1.

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment