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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Vice President- Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, NW
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MAR 20 2000

Docket No. 78N-0038

Dear Mr. Donegan:

This letter acknowledges receipt of your submissions dated January 14 and March 6, 2000, on behalf of the Cosmetic, Toiletry, and Fragrance Association (CTFA) and the Consumer Healthcare Products Association (CHPA). In addition, this letter outlines the status of related outstanding data and information previously requested by the agency.

The data and information listed below relate specifically to issues concerning the over-the-counter (OTC) sunscreen drug product rulemaking that were requested during feedback meetings on January 27, July 22, and October 26, 1999, and in feedback letters of July 16 and September 2, 1999. We also refer to the telephone conversations on January 5 and 13, 2000, between Ms. Elizabeth Anderson of CTFA and Ms. Elizabeth Yuan of the Food and Drug Administration (FDA) concerning the status of these requests.

We note receiving the following comments related to testing methodology for OTC sunscreen drug products with high sun protection factor (SPF) values:

1) Comments concerning the appropriateness of a "COLIPA solar simulator emission spectrum, with a modification to limit the energy <290 nm to <0.1%".

2) Comments concerning the appropriateness of a solar simulator total irradiance limit of 1500 watts/meter^2.

3) A "heat load" study titled "A Comparison of the Results of Testing Two Sunscreen Formulations With and Without a 50% Neutral Density Filter" that concludes there is no negative impact on dose-reciprocity and no adverse effects of thermal overload on the skin when solar simulators are operated within the parameters in #1 and #2 above.

4) Comments that both the monograph SPF 4 standard sunscreen or the SPF 15 standard sunscreen proposed by CTFA should be adequate as a laboratory methodology and procedures "control" because their purpose is not to serve as an "analytical standard." Also, comments that the proposed SPF 15 control can be prepared and assayed successfully and that use of controls with higher SPF values are not practical because of human limitations in SPF testing.

5) Comments suggesting that an SPF test panel of 20-25 subjects is adequate for testing high SPF formulations if the data fall within acceptable statistical parameters (if not definitive,

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additional subjects are added "with the requirement that ≥ 80% of the total panel provides valid data").

6) Comments concerning the appropriateness of an SPF test exposure dose format consisting of a series of "five exposure doses (at 25%, 20% or 15%, depending on SPF)".

7) Comments that "high-SPF claims should be justified by good science rather than a numerical limit".

8) Method validation data for the SPF 4 and SPF 15 sunscreen control standards using the submitted high-performance liquid chromatography (HPLC) assay.

The following outstanding data and information requested by the agency at the above mentioned meetings concerning the OTC sunscreen drug product rulemaking remain:

1) Additional high-SPF information (from the above mentioned September 2nd letter and October 26th meeting).

   a) Proposed methods for communicating in labeling the level of sun protection associated with high-SPF sunscreen drug products.

2) Information regarding your "critical wavelength" method submission (from the above mentioned July 16th letter):

   a) It was stated that "a region of the substrate at least 1 cm^2 in area will be measured (spectrometer)" or "5 individual regions of the substrate at least 0.25 cm^2 in area will be measured (spectroradiometer)." Explain why the difference in instrumentation choice would influence the number of measurements taken or the size of the area measured.

   b) Explain how the use of the quartz backing plate alleviates the incompatibility of the Transpore™ tape with certain vehicle ingredients and sunscreen application technique.

   c) Explain whether the minimal erythemal dose (MED) of 1 J/cm^2 is intended to be a weighted or unweighted dose, or how this value (1 J/cm^2) was determined.

3) Information concerning ultraviolet A (UVA) radiation testing and labeling of OTC sunscreen drug products (from the above mentioned January 27th and October 26th meetings and July 16th letter):

   a) Explain the rationale concerning the selection of the "critical wavelength" method over other in vitro UVA test methods (including the Diffey "ratio" method).

   b) Address the observation that products with significantly different absorption spectra can have similar "critical wavelength" values.

   c) Submit sunscreen product absorbency/transmission data requested for "ratio method" calculations.

   d) Provide data relative to the determination of the "pre-irradiation" dose concerning the photostability modification to the "critical wavelength" method.

e) Provide data relative to the differential "wash-off" of ingredients during water immersion or sweating (i.e., differential changes to UVB and/or UVA absorption).

f) Submit data/information relative to the "diffuse reflectance" method, including an assessment and comparison with the "Diffey methods."

g) Provide information concerning the appropriate proportionality between UVB (relative to the SPF) and UVA absorption in sunscreen products.

h) Provide feedback regarding appropriate label claims.

In addition, the following information concerning the labeling of OTC sunscreen drug products was indicated as forthcoming during the above mentioned July 22, 1999 meeting and January 5 and 13, 2000 telephone conversations:

1) Proposed labeling for make-up products that contain sunscreens.

2) Proposed label indications related to photoaging of the skin due to the sun.

We welcome your stated intent to work expeditiously on behalf of your members and to submit applicable data and information in time to complete a "comprehensive" final OTC sunscreen drug product monograph. At this time, we believe that additional feedback meetings are not necessary for the agency to continue its work. Future meetings, however, may be scheduled to resolve any issues that arise following the receipt of subsequent submissions.

Thank you for your partial response to our requests, and we look forward to the expeditious submission of additional data and information that address the issues listed above.

Sincerely yours,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

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

DATE: March 22, 2000

FROM: Director
Division of OTC Drug Products (HFD-560)

SUBJECT: Material for Docket No. 78N-0038

TO: Dockets Management Branch (HFA-305)

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

Valerie J. Miguiele for
Charles J. Ganley, M.D.

Attachment(s)