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Brussels, 20<sup>th</sup> March 2000

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

Dear Madam, dear Sir,

**Re: Comment to Docket 96N – 0277**

This letter contains the comment of Colipa to the proposed rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognised as Safe and Effective and Not Misbranded" (hereinafter "Proposed Rule").

Colipa is the European Cosmetic, Toiletry and Perfumery Association. It represents the cosmetic industry as a whole in Europe.

Colipa would like to express its sincere appreciation for the efforts of the FDA in moving forward to revise long-standing policy of the Over-the-Counter ("OTC") Review. Colipa appreciates the opportunity to provide input into a policy-making process that will ultimately affect many European products sold on the US market.

Colipa supports the principal of eliminating the geographic restriction of US marketing history as a requirement for eligibility for the OTC Review. Our letter of 20 December 1996 already supported this position in reply to the ANPR issued by the FDA.

As the FDA knows, many products that would be regulated in the United States as OTC drugs are regulated in Europe as cosmetics. In contrast to the system in the United States, a product in Europe can be either a drug or cosmetic, but not both. Primary examples of this approach are sunscreens and most OTC dental products, which are regulated as cosmetics in Europe.

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In this regard, we note the example of sunscreen products, which is instructive. We are aware that petitions have been submitted by several European companies since many years in support of inclusion of UV filtering agents marketed in Europe in the relevant OTC monograph on Sunscreen Products.

We refer in particular to the following UV-filters:

- Ethoxylated-ethyl-4-aminobenzoate or PEG-25 PABA (or UVINUL P25)
- Isoamyl p-methoxycinnamate (or NEO HELIOPAN E1000)
- 4-Methylbenzylidene Camphor (or EUSOLEX 6300)
- 2,4,6-Trianylino-p-(carbo-2'-ethylhexyl)-1-oxil-1,3,5-triazine or Octyl Triazone (or UVINUL T150)

In the course of FDA consideration of these petitions, the Agency has never indicated any concerns related to the European regulatory status of sunscreen products as cosmetics. The sole issue standing in the way of their substantive consideration for OTC monograph eligibility was that their marketing history was in Europe and not in the United States. The newly proposed policy, of course, removes this arbitrary barrier, which will hopefully not be replaced by another. We also emphasise that all four filters have been thoroughly reviewed for their safety by the EU Scientific Committee on Cosmetic Products and Non-Food Products and have subsequently been put on the positive list of UV-filters (Annex VII of the EU Cosmetics Directive).

As regards monitoring for safety under conditions of marketing, similar to the FDA requirements applicable to OTC monograph drugs, European manufacturers and distributors of cosmetics must keep records of reports of safety concerns. Just as in the United States, there is no mandatory reporting requirement, though authorities have exhibited a wide margin of safety and an excellent safety record. In conclusion, we believe that European marketing history for cosmetic products, which would be regulated in the United States as OTC drugs, should be accepted to support eligibility for the OTC Review.

The existing US regulations on sunscreen products and in particular UV-filters have denied and still deny US consumers access to newer and higher performing UV-filters. The NDA route is not suited at all for cosmetic ingredients, which are employed in a wide spectrum of formulations, continuously adapted to changing situations in terms of product composition and consumer preference. It is therefore critical that the new OTC Review criteria encourage entry of safe and effective sunscreen products onto the market rather than to impose hurdles in terms of data requirements and eligibility rules.

Concerning the Proposed rule on extent of marketing (proposed 330.14(c)(2)(ii)) the requirement to indicate the number of dosage units sold is excessive and should be replaced by total quantity of product sold, with an extrapolation then being made to the number of consumer units, based on average pack size.



The Proposed rule requires information on geographical and cultural influences (proposed 330.14(c)(2)(iii)). Again, it should be possible to refer to larger areas and the population of the EU represents sufficient variability in terms of culture and gender to obtain adequate feedback on population exposure.

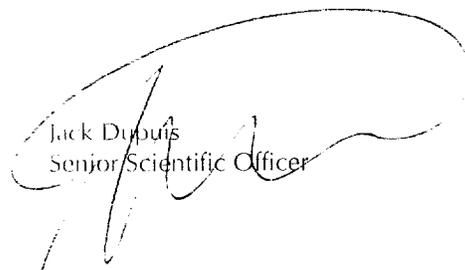
The Proposed rule on marketing history (proposed 330.14(c)(3)) will be difficult if not impossible to obtain. We therefore ask the agency to consider the limitation of data provision to a review of time and extent of marketing.

Colipa is very concerned that the Proposed rule does not lay down time limits for review of data to be submitted under the new criteria. Existing history with petitions, dating back to more than twenty (20) years ago, demonstrates a future need for timely progress in this matter. We do hope that the Agency will take seriously into consideration the need for well-defined timings to progress with the newly established criteria. This is especially critical if the Agency will not permit interim marketing of products concerned.

Colipa strongly supports third party review of submitted data under the Proposed rule, as a means to avoid spending undue time within the established procedures.

Colipa believes that the establishment of criteria for eligibility based on foreign marketing data is overdue. Colipa is confident that European marketing history should be more than sufficient to allow addition of the four listed UV-filters to the existing US Sunscreens OTC Monograph.

Sincerely Yours,



Jack Dupuis  
Senior Scientific Officer



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