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August 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 78N-0038
Sunscreen Drug Products for Over-the-Counter Human Use

Neutrogena Corporation submits these comments in response to the reopening of the administrative record on Sunscreen Drug Products for Over-the-Counter (OTC) human use. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record. 65 Fed. Reg. 36319 (June 8, 2000).

Neutrogena Corporation is requesting that as part of the reopening of the administrative record on sunscreens, FDA consider these issues related to:

- 1) High sun protection factor (SPF) values over 30,
- 2) Skin aging indications outside of the "Sun Alert" box,
- 3) Additional sun protection indications,
- 4) Product appropriate directions for use, and
- 5) UVA test method and labeling.

High Sun Protection Factor (SPF) Values

Many consumers have made an educated decision to make SPF 45 sunscreens their primary purchase for sun protection. For the year to date, July 23, 2000, Information Resource Incorporated (IRI) data indicates that SPF 45 products are the top two products purchased by consumers. Products with SPF 30-44 are the largest segment of the market, currently comprising 35% of the total sunscreen market. Products with SPF 45 are the one of the fastest growing segments (up 13% vs. a year ago), currently comprising 20% of the total sunscreen market. It is clear that consumers are choosing to protect themselves from the harmful rays of the sun, and part of that decision involves using sunscreen products with high SPF values. As consumers clearly demand high SPF, it seems inappropriate to bar manufacturers from claiming information on the label that is substantiated by solid scientific evidence and that consumers clearly find to be beneficial.

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Concerns have been raised regarding consumer misuse of high SPF sunscreen products. This concern is based on the perception that consumers will spend more time in the sun due to high SPF protection, potentially exposing themselves to more UV damage.

In order to help reduce potential consumer misuse, Neutrogena recommends that high SPF sunscreen products should be allowed to claim accurate SPF values over 30 that are supported by valid scientific evidence. Additional labeling that educates consumers regarding the safe use of high SPF sunscreens should be required on all products with a sunscreen with a SPF above 30. The required labeling is suggested, but not limited to “High SPF products give more sun protection, but are not intended to extend the time spent in the sun”.

Another concern has been raised regarding the prices that consumers must bear for higher SPF products. There is a misconception that cost increases in relation to SPF benefit. Neutrogena sunscreen products intended for recreational use, whether they offer SPF protection 15, 30, or 45 are all currently sold at the same price point. Further, Neutrogena facial moisturizers with sunscreen are currently sold at the same price point as the equivalent formula without sunscreen. In summary, consumers are not being incrementally charged, based on the level of sunscreen protection imparted by a product.

Skin Aging Claims Outside the “Sun Alert” Box

It is widely understood that sun induced skin damage can contribute to photoaging and the increased risk of skin cancer. The Agency has recognized this fact in the final UVB sunscreen monograph in which allows the optional statement “Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun”.

It is important for manufacturers to be allowed to display truthful uses in the labeling of sunscreen products. Neutrogena urges the Agency to allow such truthful indications, such as:

- ✓ helps protect against skin damage caused by the sun
- ✓ helps protect against skin aging caused by the sun
- ✓ regular use helps protect against certain forms of skin cancer caused by the sun
- ✓ helps protect against fine lines and wrinkles caused by the sun
- ✓ helps protect against pigmentary changes due to sun exposure.

Additional Sun Protection Indications

Not all consumers purchase sunscreen-containing products for sunburn protection. For example, consumers who use color cosmetics or facial moisturizers with sunscreens make the informed decision to purchase them as an additional benefit to their cosmetic use. There are a significant number of persons with dark skin types (for example: Fitzpatrick Type IV - VI) who do not easily burn. These consumers purchase sunscreen products in order to provide protection from the sun damage that is not immediately recognizable.

For these reasons, Neutrogena urges the Agency to allow such truthful indications such as:

- ✓ helps protect against casual or incidental or intermittent daily sun exposure
- ✓ helps protect against the harmful effects of the sun.

Product Appropriate Directions for Use

The information found under “Directions” as they are written in the final rule, do not provide flexibility for products that are intended to provide sun protection as an additional benefit to their cosmetic use. Consumers who purchase color cosmetic products or moisturizers with sunscreens do not apply them, as would a consumer who is applying a sunscreen product primarily intended for use during recreational outdoor activity. As a result, directions that are appropriate for recreational outdoor activity, or for products that are intended to be used primarily as protection against sunburn require a separate set of directions than do those intended for incidental sun exposure.

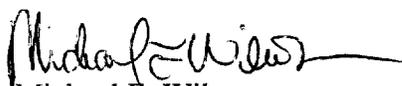
Neutrogena suggests additional options under the “Directions” section of the monograph such as, but not limited to, “apply smoothly or evenly before sun exposure and reapply as needed”. This will provide consumers of color cosmetic products or moisturizers containing sunscreen with directions that are more in line with an actual daily use regimen.

UVA Test Method and Labeling

We support the comments endorsed by our parent company, Johnson & Johnson, and our industry associates Schering-Plough, Estee Lauder, L'Oreal, and Bath & Body Works regarding UVA testing and labeling, as well as the comments filed by our industry manufacturer's association, the Cosmetic, Toiletry, and Fragrance Association.

In closing, Neutrogena Corporation strongly urges the Agency to consider that consumer demand and scientific evidence supports the need for consumers to have access to high level UVA/UVB sunscreen products to provide protection from the damaging effects of the sun. High SPF products (SPF over 30) can be substantiated with the assurance that they are providing the claimed protection. In conjunction with the labeling indications and directions that have been suggested, consumers can continue to benefit from the high SPF products that they rely upon today.

Respectfully submitted,


Michael F. Wilson
Regulatory Affairs Manager

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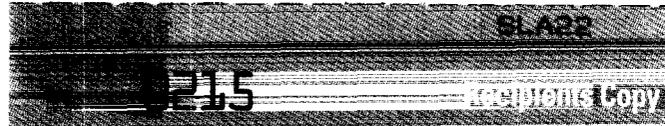
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