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July 21, 2003

Submitted Electronically and Via Federal Express

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

Re: **Federal Register Notice of Intent; Docket No. 02N-0434**

Dear Sir or Madam:

On April 22, 2003, the Food and Drug Administration (FDA) published a Notice of Intent to withdraw 84 Proposed Rules, including a Notice of Proposed Rulemaking (NPR) entitled, "Cosmetic Products Containing Certain Hormone Ingredients", which was originally published on September 9, 1993.[1] We believe that the withdrawal of this NPR is unjustified and would have a detrimental effect on the ability of women to obtain and use safe cosmetic products that they have relied on for over 40 years. Accordingly, on behalf of the Institute for Graceful Aging, we respectfully request that the Commissioner of FDA not withdraw this initiative, but instead, direct that it be finalized by the Agency.

As FDA is aware, the genesis of the NPR on cosmetic products containing hormone ingredients began with the establishment of the Over-the-Counter drug monograph, "Topically Applied Hormone-Containing Drug Products for OTC Use".[2] However, it became clear to FDA after the monograph review process had begun that most of the topical, hormone-containing products on the market were marketed as cosmetics and not as drugs. For this reason, FDA chose to convert its review of topically applied hormone-containing drug products to a review of cosmetic products containing certain hormone ingredients. This was accomplished when FDA published a negative Final Rule on Topically Applied Hormone-Containing Drug Products for OTC Use on September 9, 1993,[3] and that same day, also published a Notice of Proposed Rulemaking (NPR) on cosmetic products containing certain hormone ingredients.[4]

[1] 58 Fed. Reg. 47611 (September 9, 1993).
[2] 47 Fed. Reg. 430 (January 5, 1982).
[3] 58 Fed. Reg. 47608 (September 9, 1993).
[4] 58 Fed. Reg. 47611 (September 9, 1993).

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Clearly, when FDA published the NPR, the Agency made a commitment to consumers to establish standards for the safe and appropriate marketing of cosmetics containing hormone ingredients. Indeed, in the NPR, FDA stated that its Advisory Panel on OTC Miscellaneous External Drug Products "recommended that FDA regard progesterone in a concentration up to 5 milligrams (mg) per ounce (oz) as safe when used on the skin daily in a quantity not exceeding 2 oz per month".[5] The Panel also stated that "topical progesterone does not produce systematic effects and has a low incidence of irritation or allergenic local effects". Further, the Panel noted that it had reviewed FDA's adverse reaction files for topical hormone-containing products, and that "none of the occurrences was classified as serious".[6] These Advisory Panel recommendations clearly indicate that, at the time the NPR was published, the Panel had already spent considerable time and effort reviewing data and information on cosmetics containing hormones. FDA should not now abandon the work and recommendations of its own Advisory Panel. Instead, FDA should move forward and finalize a regulatory initiative involving products that have been used safely by women across America for decades.

As stated above, cosmetics that contain hormone ingredients have been marketed safely in the United States for over 40 years. Hormone ingredients perform legitimate and appropriate functions in cosmetic products - e.g., often functioning as humectants and skin conditioning agents. Hormone ingredients can also provide needed texture to topical product formulations, and/or serve as production aids during the manufacturing process. Moreover, hormone ingredients have been widely used in cosmetic formulations for many years and no issues related to their safe use have arisen. In view of this positive safety profile, FDA has no compelling reason not to renew its commitment to providing American consumers with a definitive regulatory assessment of cosmetics that contain hormone ingredients.

For the reasons set forth above, it would clearly be of public benefit for FDA to continue its rulemaking on cosmetics containing certain hormone ingredients. FDA can begin the rulemaking process by taking stock of the data it initially reviewed on cosmetic products containing hormone ingredients in order to determine what type of data is still needed to complete the rulemaking. After such an assessment, FDA could then issue a "Call For Data", which would allow industry to provide FDA with any new data on cosmetics containing hormone ingredients, or hormone ingredients individually, that has been developed over the past 10 years. After these initial steps, FDA would be able to move forward towards the publication of a Final Rule.

On the basis of the above discussion, the Institute for Graceful Aging respectfully requests that FDA reconsider its intent to withdraw this rulemaking and instead continue with the important work begun in 1993 with the initial publication of the NPR. Indeed, continuation of the rulemaking is the appropriate next step for the Agency on this matter. It will help consumers and

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[5] Id.
[6] Id.

the industry by ultimately providing a clear standard to guide choices with regard to the proper levels of progesterone, pregnenolone acetate and any other hormone ingredients used to formulate cosmetics. This is also the only way that we can be sure that these cosmetics will continue to be both available and used appropriately by women. By bringing its scientific resources and responsible authority to bear in the form of a Final Rule, FDA will be serving the public health needs of Americans.

Thank you in advance for your consideration.

Sincerely,

Georgia C. Ravitz
Counsel, Institute for Graceful Aging

cc: Tommy G. Thompson, Secretary of Health and Human Services
Mark B. McClellan, FDA Commissioner
Daniel E. Troy, FDA Chief Counsel