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July 21, 2003

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

**Re: Docket No. 02N-0434; Cosmetic Products Containing Hormone
Ingredients**

Dear Sir or Madam:

On behalf of Women Supporting Choice, we strongly urge the Food and Drug Administration (FDA) not to withdraw a proposed rule on cosmetic products containing hormone ingredients, 58 Fed. Reg. 47611 (Sept. 9, 1993) (Cosmetic Proposed Rule). We understand FDA proposed to withdraw this Cosmetic Proposed Rule as part of FDA's Notice of Intent to Withdraw Certain Proposed Rules and Other Proposed Actions, published at 68 Fed. Reg. 19766 (April 22, 2003).

FDA's notice to withdraw the Cosmetic Proposed Rule mechanically and without any consideration of its merits contravenes its own policies as well as those of the Bush Administration. FDA officials recently indicated that the Agency wants to offer more choices and opportunities for consumers and marketers, as long as the products are safe and effective. Additionally, FDA and the Bush Administration have each indicated that its regulatory policy will address the special concerns of small business.

FDA acknowledged in its proposed rule that cosmetic products containing hormones are marketed and used by American consumers. Comments on the proposed rule confirm this and explain some of the benefits of these products. Women Supporting Choice strongly supports the continued availability of such products for all consumers, but especially older women, to allow them the option of using and purchasing cosmetics containing hormones. Such products provide beautifying and improved appearance benefits that can be a part of a natural approach to health and vitality.

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In its Cosmetic Proposed Rule, FDA indicated that such products merit cosmetic status. FDA has not referenced any studies, specific concerns, or other evidence supporting a change in position. Accordingly, Women Supporting Choice submits that it would be arbitrary and a fundamental denial of choice to American consumers for FDA to withdraw the Cosmetic Proposed Rule.

Women Supporting Choice supports choice in the American marketplace. We are not aware of any safety or efficacy issues with cosmetics containing hormones. Accordingly, we strongly urge FDA to preserve the choice for American women who wish to continue using cosmetics containing hormones.

In any event, to the extent that FDA offices with responsibility for this product category, including the Office of Cosmetics and Colors, have not been fully consulted regarding abandonment of this rulemaking, we respectfully submit that their input should be sought. It would be unfortunate if this cosmetic choice were foreclosed without consideration of its merits and without concurrence from those who have worked on it or work in this area.

Adverse Effects of Withdrawal

FDA's withdrawal of the Cosmetic Proposed Rule could call into question the right of consumers to obtain cosmetics with hormone levels deemed safe by both an expert panel and FDA itself. Further, withdrawal of the Cosmetic Proposed Rule could call into question many of FDA's findings contained in the preamble to the Cosmetic Proposed Rule. For instance, the Cosmetic Proposed Rule contains language indicating that cosmetic use is safe. Withdrawal of the proposed rule and abandonment of the rulemaking could be used by critics to call into question these positive findings about the cosmetic use of hormones.

The Cosmetic Proposed Rule cannot be viewed in isolation. It was proposed at the same time FDA proposed a rule prohibiting the marketing of topically applied hormone-containing drug products for OTC use. This "sister rule" was finalized. Withdrawal of the Cosmetic Proposed Rule might lead to the erroneous conclusion that cosmetic use of hormones is illegal or suspect. Even without reaching this erroneous conclusion, it is likely that a withdrawal of the Cosmetic Proposed Rule will make it harder to market and obtain safe and useful products.

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FDA proposes to withdraw the Cosmetic Proposed Rule without specific consideration of its merits. Instead, FDA's notice of intent to withdraw this rulemaking is merely part of a general housekeeping withdrawal of 84 proposed rules and other notices. In effect withdrawal is a choice for FDA that denies consumers the choice of safe products. FDA acknowledges, in its withdrawal notice, that the Agency is "not required to [withdraw the proposed rules] by the Administrative Procedure Act or by regulations of the Office of the Federal Register." Rather, FDA is "cleaning the docket" of many old or supplanted proposed rules. The Cosmetic Proposed Rule should not be lumped into this "housekeeping" category simply to clear administrative backlog. As noted above, the potential harm is great. In contrast, there is little cost to FDA continuing to proceed with this rulemaking.

We submit that prioritization and housekeeping, while necessary, should not be achieved at the cost of women's right to choose to use beneficial products. The continued availability of cosmetic products containing hormones is important to many people, especially many women over 40 years old. Although the regulation of such products may not be as high a priority as fighting bioterrorism, neither should regulation of a product category be abandoned without any consideration.

The Cosmetic Proposed Rule is not one of the oldest rules, nor is it one of the rules that were previously identified for withdrawal. Unlike other proposed rules, it has not been supplanted by other laws or regulatory actions, and FDA has not completed action on any other regulatory alternative.

Small Businesses Would Be Adversely Effected by Withdrawal

Withdrawal of the Cosmetic Proposed Rule would adversely affect small businesses' ability to market cosmetics. This counters the argument FDA used to address small business concerns identified with the final rule on Topically Applied Hormone Containing Drug Products for Over-the-Counter Human Use (Drug Final Rule). In the Drug Final Rule, the FDA suggested small businesses have a cosmetic option:

The agency is aware of only a few other products that are currently marketed without new drug applications. These products would be able to remain in the market with some relabeling in accord with the notice of proposed rulemaking for cosmetic products containing certain hormone ingredients, published elsewhere in this issue of the Federal

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Register. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

58 Fed. Reg. 47608 (Sept. 9, 1993). Cutting back on the cosmetic hormone option undermines this earlier position.

The existence of the Cosmetic Proposed Rule was a justification for not performing a regulatory feasibility analysis under the Regulatory Flexibility Act (Pub.L. 96-354). Withdrawal of the Cosmetic Proposed Rule removes a justification for not reviewing the impact on small businesses for the existing Drug Final Rule and, in fact, would adversely affect the many small businesses that market, supply and sell cosmetics with hormones.

Further, lack of uniform federal regulations could provide an opportunity for the states to enact inconsistent regulation over products marketed under the Cosmetic Proposed Rule. This would make it more difficult for marketers to sell cosmetics containing hormones on a nationwide basis.

FDA's offer that manufacturers and marketers can submit a citizen petition to undertake rulemaking in the future on this issue is not practicable for small businesses currently marketing this product. Rather, the impact will be too great: many small business will not be able to submit a citizen's petition or otherwise be able to explain to distributors or retailers the legal backing for these useful cosmetic products. Instead, many small businesses would cease marketing these types of products and perhaps even cease to operate as a business. Because most of the manufacturers and marketers of hormone cosmetic products marketed under the Cosmetic Proposed Rule are small businesses, the withdrawal of the Cosmetic Proposed Rule could be devastating.

Conclusion

Women Supporting Choice strongly urges FDA to reconsider withdrawing the Cosmetic Proposed Rule because such withdrawal is arbitrary and inconsistent with FDA



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policies and statements. On a practical level, such withdrawal will deny American consumers a choice and adversely impact American small businesses.

Respectfully submitted,

A handwritten signature in cursive script that reads "William C. Waller".

William C. Waller

cc: Tommy Thompson, Secretary of HHS
Mark McClellan, FDA Commissioner
Dan Troy, FDA Chief Counsel

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