AMERICAN ASSOCIATION FOR
HEALTH FREEDOM
FORMERLY THE AMERICAN PREVENTIVE MEDICAL ASSOCIATION

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June 23, 2003

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 Dockets Management Branch:

I am writing on behalf of the American Association for Health Freedom (AAHF), a nonprofit advocacy organization dedicated to achieving health care freedom for all Americans. We work at the federal level to increase consumers' access to complementary and alternative medicine (CAM); to information about their health care options; and to practitioners who provide a nutritional and holistic approach to health care and disease prevention. We also promote legislation and regulations that protects the rights of practitioners to offer safe, non-conventional therapies, and legislation that increases the quality and quantity of research on CAM. Our membership includes medical doctors, osteopaths, chiropractors, naturopaths, dentists, nutritionists, acupuncturists, doctors of Oriental Medicine, massage therapists, consumers, pharmacies, labs, manufacturers and others in 48 states and four foreign countries.

I am writing in opposition to your April 22, 2003 declaration of intent to withdraw the proposed rule pertaining to Cosmetic Products Containing Certain Hormone Ingredients; – Docket No. 91N-0245. For the past decade, numerous safe and effective personal care products have been available under this rulemaking to meet the needs of the ever-growing population of women over 50. These women seek ways to look and feel better about themselves, to take responsibility for their health, to extend their lives, to prevent disease, and to remain active into their twilight years. Cosmetic products available under this rulemaking are an important and valuable part of their healthful regimen. Millions of women should not be denied the right to use these cosmetics unless FDA has compelling evidence that these products are unsafe. Years of safe use belies the need to eliminate them from the market now and, indeed, should compel the agency to proceed with the rulemaking.

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Based on the Notice published, it does not appear that FDA has evidence or concerns that these products are unsafe. Indeed, in FDA's Notice of Intent to withdraw the rulemaking, the agency stated that it is taking this action simply "to reduce its regulatory backlog...." While we understand the agency's desire to clear its docket, we are concerned that, in this instance, it will amount to throwing the baby out with the bath water. An entire category of safe and effective products will be completely eliminated in an effort to reduce a paperwork backlog caused by FDA's limited resources.

The agency also stated in its Notice that it would like to "...focus its resources on current public health issues." We can only surmise that those public health issues have been deemed more pressing than ensuring continued public access to a particular type of cosmetic. While we agree that focusing on bioterrorism issues certainly trumps access to cosmetics, and while we understand that the agency must prioritize its resources to ensure that the most critical needs are addressed, we also believe that keeping this rulemaking alive would consume so little of the agency's resources and at the same time result in such tremendous benefits to millions of women, that it is worth pursuing.

We also believe that this issue deserves a full and fair vetting before FDA withdraws this rulemaking, in order to ensure that FDA does not pursue a decision that would have unwanted and unanticipated effects on millions of women. This issue may not be high profile or on par with life-threatening diseases, but it nevertheless deserves full review to ensure that the many companies that have relied on this rulemaking are treated with the fairness that the agency's rulemaking process usually provides.

We respectfully request that FDA reconsider its intent to withdraw this rulemaking and instead continue with the rulemaking begun in 1990. This will give industry the opportunity to share important information and data with FDA, and ensure that the agency makes an educated decision after careful review. We believe that continuation of the rulemaking is the appropriate next step for the agency on this issue. 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 a significant percentage of the population.

It seems clear from the initial notice of proposed rulemaking that FDA planned to finalize a rule; that intent should not be lost in an effort to address docket overload. It is our hope that FDA will follow through on its original plan and allow the rulemaking process to go on to completion.

Thank you in advance for your consideration.

Sincerely,

Candace Campbell

Candace Campbell
Executive Director

Cc:

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