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June 30, 2003

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

Re: Withdrawal of Certain Proposed Rules and Other Proposed Actions;
Notice of Intent; Docket No. 02N-0434, 68 FR 19766 (April 22, 2003)
and
Sub Docket No. 91N-0245, 58 FR 47611 (September 9, 1993)

Dear Sir or Madam:

As health professionals and advocates for women consumers, we would like to state our opposition and concern over the recent Notice (**Docket No. 02N-0434**) sent by your office to withdraw a rule (**Docket No. 91N-0245**) that currently allows women access to cosmetic topical progesterone products. We urge you to not withdraw this ruling. We are health care professionals dedicated to helping patients exercise personal autonomy and choice in health care; we believe that withdrawal of this ruling will ultimately have a devastating effect on women consumers across the county. Taking away this rule would create unnecessary restrictions on women and limit their freedom to choose, purchase and enjoy these products as a way to look and feel better.

Moreover, your decision to potentially take away this consumer right seems arbitrary. The "reasons" stated in your letter are not based on fact or information, but rather a desire by the FDA to "reduce its backlog of paperwork" and to "focus its resources on public health issues." While we can appreciate FDA's desire to clear paperwork and focus on important "public health issues," those statements coupled with the intent of the Notice leads us to believe that your office may not understand the critical importance and value these products have for women.

Annually, more than a half a million women freely choose to use these products. Each year that number grows, as more women age and seek out these products as a personal choice for their well-being. For them, this is a personal issue and a personal choice. They do not want this choice taken away.

2002N-0434

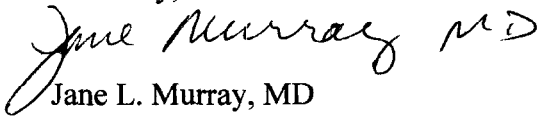
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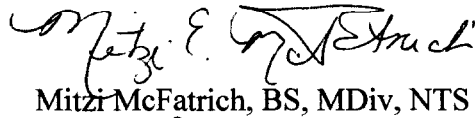
If FDA seeks to take away a ruling that has allowed access to these products, it should first provide all compelling evidence as to why these particular products should be limited. The Notice does not show any such evidence. The FDA Notice does not reference new scientific studies supporting a withdrawal of the rule nor did it state that it had additional information concerning the safety of these cosmetic products.

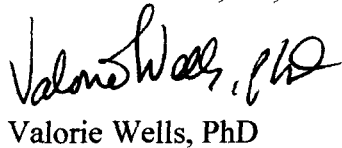
Therefore, we respectfully urge you to reconsider the value of these products to women consumers and not withdraw this rule.

We truly appreciate your consideration of this matter.

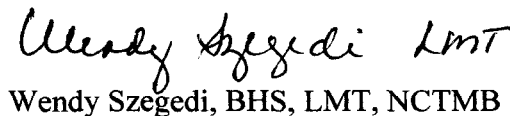
Sincerely,

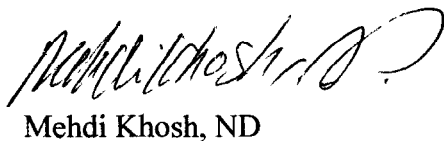

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Cc:

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