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**Grace Meng**

**Congress of the United States**

**Sixth District, New York**

October 31, 2016

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Dr. Robert M. Califf  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf:

I write to request that manufacturers of feminine hygiene cosmetics be prohibited from using unsafe colorants in their products, and that you issue appropriate guidance on the use of colorants in these products. I also ask that the labeling of such products be required to display more accurate usage and ingredient descriptions. These requests mirror those made in the citizen petition submitted to you by Women's Voices for the Earth on August 17, 2015.

The U.S. Food and Drug Administration (FDA) currently considers feminine hygiene cosmetics such as feminine washes to be "externally applied" products. However, in order to attain desired results, female anatomy necessitates internal application of these products, an observation supported by marketing language such as "pH balanced" or "helps maintain a healthy pH balance" that routinely appears on feminine wash labels and in product advertisements. There is no reason for these statements unless these products are intended to be used internally.

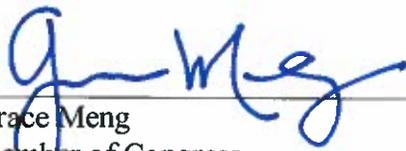
This realization is troubling because FDA's treatment of feminine washes as "externally applied" products permits manufacturers to include colorants in their products, specifically D&C Red No.33 and Ext. D&C Violet No. 2, that are only approved for external cosmetics and may cause negative health effects when used incorrectly. It also permits usage of FD&C Yellow No. 5 in cosmetics without a labeling requirement. Though FD&C Yellow No. 5 is approved to be used in all cosmetics, it is required to be labelled when used in prescription products inserted vaginally. Because feminine care cosmetics are also applied inside the vagina, it follows that the FDA should require FD&C Yellow No. 5 to be labeled on these products as well.

Many women have complained of skin irritation, rashes, and other side effects when using feminine cosmetic products containing these three colorants. But for the miscategorization of feminine washes and similar products, American women would not unknowingly insert potentially harmful chemicals into their bodies. I ask, therefore, that you address this problem by

acknowledging the fact that feminine washes, and similarly situated feminine hygiene cosmetics, are not “externally applied” products. Once you have, I ask that updated labelling and ingredient listing guidance be issued to manufacturers.

I look forward to working with you to protect the health of all American women, and ask that you notify my office when the changes requested in this letter have been implemented. I further ask for notification when a formal response has been issued to Women’s Voices for the Earth’s citizen petition. You may contact me anytime, and your staff may contact Genevieve Morton of my staff at [genevieve.morton@mail.house.gov](mailto:genevieve.morton@mail.house.gov) or (202) 225-2601.

Sincerely,



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Grace Meng  
Member of Congress