L'ORÉAL
USA

August 10, 2005

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

Re: [Docket No. 2005N-0217]; 70 F.R. 34142, June 13, 2005
Comment Request: Cosmetic Product Voluntary Reporting Program

Dear Docket Officer:

Thank you for the opportunity to respond to a request for comments concerning 21 CFR 720 (Voluntary Filing of Cosmetic Product Ingredient Composition Statements).

L'Oréal USA Products, Inc. respectfully submits the following comments on the collection of information associated with the Cosmetic Product Voluntary Reporting Program:

Topic: Ways to enhance the quality, utility, and clarity of the information to be collected

1. *Product categories*
   (21 CFR 720.4(a)(4))
   Product categories need to be revised. The types and forms of products have evolved over the years and this needs to be reflected in the product category choices. With regard to "form", where only lotions and creams may have once existed, there are now forms such as balms and gels.

   Currently, categories do not contain all possible "forms" (i.e., "creams", "gels", "balms", "lotions", etc.). To eliminate the same problem from appearing again in the future when additional "forms" emerge, categories should become more "general" (eliminating "forms" [i.e., "lotions", "creams", etc.] and replacing with general terms such as "products").

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For example, an aftershave balm would be excluded under the current rules from 720.4(c)(11)(i) since that category only contains "aftershave lotions", even though that would be the most appropriate category designation since the product's function/use is the same, regardless of the form. This issue could be resolved by renaming the category "aftershave products".

In the same respect, "lipstick" should change to "lip products" under the "makeup preparations excluding eye" category so that products like lip gloss and lip pencils can be included here.

However, in some instances, additional product categories need to be created. For example, with regard to product type, there are 2-in-1 products such as a "shampoo and conditioner" that do not currently have a product category. Also, while there is a category for hair "grooming aids", there is no category for hair "styling" products.

Regardless of the type of revisions (creating needed new categories or grouping products into more general categories), the end result would be the same: information obtained will be more accurate and will be available more quickly.

2. *Ingredients in the product*
   (21 CFR 720.4(a)(5))
   The regulation only states that the ingredients in the product be provided. However, Form FDA 2512a requires the "9-digit CAS number" in addition to the common/chemical name. The requirement for both the ingredient name and the CAS number is onerous. As a rule, many of our products contain many ingredients; it is burdensome to not only type each ingredient onto the form, but also to then match each to its respective CAS number. Again, it would be a more efficient program if only the ingredient name need be provided.

3. *Separate forms for hair coloring preparations with the same ingredients including colorants where only the amounts of the color additive ingredient used are varied*
   (21 CFR 720.4(e))
   The regulation states that only one Form FDA 2512 be submitted for cosmetic products other than hair coloring preparations if only the amounts of the color additive ingredient used are varied. If the same is true for hair coloring preparations, i.e., only the amounts of the color additive ingredient used are varied, only one form should be submitted as well.

We have many shades of hair coloring preparations and this change would greatly increase the speed with which this information could be submitted to the FDA under this voluntary program.

Also, the FDA would still be receiving all the information (ingredients and product names) necessary to help the Agency "in its mission to protect consumers, while also helping cosmetic manufacturers and distributors make informed decisions." Potentially harmful, prohibited, or restricted ingredients would still be readily identifiable as would the product or products that contain those ingredients.

4. *Designation of page numbers*
   (Form FDA 2512a)
   The current Word version of this form does not allow for manipulation of the "Page __ of ___ Pages" footer; therefore, this has to be added manually. Generation of consecutive pages should be incorporated into the document or at least a running footer where only the blanks need be filled in instead of someone having to manually write, for example, "Page 1 of 17 Pages", etc. on each consecutive page.

Topic: Ways to minimize the burden of the collection of information on respondents

1. *Creation of An Electronic Format/System*
   Since the current paper format is time-consuming to complete and to some extent redundant in the sense that the company uses an electronic format to obtain the information it needs to then put on paper to mail, and the FDA undoubtedly then enters this information into an electronic format, creating an electronic format that allows information to be sent directly electronically and then manipulated into an FDA database would be more efficient and more accurate.

2. *Improvement of An Electronic System Over the Existing Paper Format*
   An electronic format, however, needs to be more than an electronic version of the current paper format.

   Ideally, it would be more efficient, more accurate and more practical if a file could be attached to a field/screen requesting a product's ingredients, perhaps a system that could incorporate some sort of information transfer system or "mass import", maybe via Excel or an XML Web interface whereby data would be imported into the FDA's database from the company's database. This would greatly speed up the process and participants would then be able to provide the FDA with much more information at a much more rapid pace.

In addition, this electronic format would incorporate the requested changes noted above with regard to enhancing the quality, use, and clarity of the information to be collected.

In summary, we hope that in reviewing this program, the FDA will take the opportunity to maximize the efficiency and accuracy of the information it seeks for all concerned parties.

Again, we appreciate the opportunity to comment on these issues. If you would like to discuss these comments in further detail or if you have any questions concerning these comments, please contact me by phone, letter, or e-mail, as noted below.

Sincerely,

Deborah Edick

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