USER FEES FOR OTC DRUGS

Good morning. I am Mark Pollak, Senior Executive Vice President – Strategic Initiatives of the Personal Care Products Council. Our member companies manufacture and/or distribute cosmetics, toiletries, fragrances, and personal care products, as well as supply ingredients to the industry and are very interested in the subject of this hearing.

PCPC acknowledges that the OTC monograph system could be modernized.

Nonprescription OTC drugs under the monograph system are not subject to approval by FDA prior to marketing, so there are thousands of such products currently on the market. Our members feel strongly that any monograph reform needs to avoid any disruption of the market for these existing products. Reform also must be balanced so as not to impair industry's ability to innovate.

The current rule making process is slow. We believe that FDA can better protect the public health by completing monographs in tentative status and making necessary labeling changes in a timely fashion.

Consumers need assurance that the regulatory system works for them and continues to allow them access to OTC drug products that they use on a regular basis.

PCPC recognizes that FDA is critically under-resourced for regulating nonprescription OTC drugs under the monograph system. PCPC is open to a thorough discussion and study of a user fee program for nonprescription OTC drugs. It is important that any program avoids double fees for cosmetic-drug products since the proposed Feinstein-Collins legislation contains provisions for user fees for cosmetic products, and it would be unfair to require fees from companies twice for the same product.

We acknowledge that additional resources for FDA could result in potential benefits to public health and that user fees can create incentives or disincentives for certain activities. However, any fee proposal must be fair and balanced, must establish clear identification of products subject to the program, and be tailored to the unique needs of this discrete set of products.

The focus of fees should not target long-standing actions that FDA has yet to complete, such as monographs that are not yet finalized.

With regard to user fees in general, FDA's application of fees must be transparent, so that it is clear what they are spent on, and trackable, that is measurable, transparent and understood by industry.

In conclusion, FDA and industry must work together to establish specific goals/metrics tied to the collection of any fees. Any user fees should target innovation while the appropriations budget should cover long-standing actions, such as monograph finalization and maintaining capabilities.

Thank you for the opportunity to share our comments.