CHPA

founded 1881

October 31, 2011

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

Re: Docket No. FDA-2010-N-0128, Prescription Drug User Fee Act; Request for Comments

Dear Sir or Madam:

In the September 12, 2011, *Federal Register*, the Food and Drug Administration invited comments on proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA). The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of nonprescription or OTC medicines and dietary supplements in the United States, including OTC medicines under new drug applications (NDAs) and supplemental NDAs containing clinical data subject to user fees. CHPA members account for over 90 percent of the domestic retail sales of OTC medicines. As such, we have an interest in the subject matter of the proposed rule.

We understand that, as stated by Dr. Janet Woodcock, director, Center for Drug Evaluation and Research, at the October 24, 2011, public meeting on PDUFA reauthorization, FDA's proposed recommendations for PDUFA reauthorization center on process, procedure, and resources. We have two process or procedure recommendations for the agency.

1. FDA should expand the program for new molecular entity enhanced review transparency and communication to include all efficacy supplements for which an advisory committee meeting is scheduled. There are comparatively few NDAs or supplemental NDAs that trigger the need for an advisory committee meeting, but most first-in-class prescription-to-OTC switch NDAs *are* the subject of advisory committee meetings. Late cycle communications processes are particularly critical to meet timelines and data presentation expectations for any NDA, including for Rx-to-OTC switches, that has an

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advisory committee. We do not, however, see a need for Rx-to-OTC switch NDAs to be included in the 60 day administrative filing review period for new molecular entity NDAs and BLAs, since an initial prescription NDA would have already been approved by the agency. Given that there are fairly few NDAs that meet these criteria, this should not create a significant workload issue for the agency.

2. Second, we recommend that first cycle review performance measurements be reported by Division or Office, rather than solely in an overall CDER performance measure. This would serve to increase transparency.

These two modest process or procedure changes would serve to advance the PDUFA goal of timely review of the safety and effectiveness of NDAs with minimal resource impact on the agency.

We appreciate the opportunity to submit these comments.

Respectfully submitted,

David C. Spangler
Senior Vice President, Policy, and
General Counsel & Secretary

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