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Associate Vice President,
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November 29, 2004

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

Re: Docket Number 2004D-0410; Draft Guidance for Industry and Food and Drug Administration Staff: Application User Fees for Combination Products; Availability; 69 Federal Register 57942; September 28, 2004

Dear Sir/Madam:

The following comments on the above noted draft Guidance are submitted on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. Our member companies are devoted to inventing medicines that allow patients to lead longer, happier, healthier, and more productive lives. In 2003, our members invested over \$33 billion in the discovery and development of new medicines.

PhRMA does not object in general to the levying of 2 User Fees for those rare occasions when two separate applications are deemed (by sponsor or FDA) to be necessary.

PhRMA acknowledges and supports the avenues (albeit limited) that are currently available to sponsors to seek relief from User Fees. However, we raise an equity issue with regard to the overly constraining eligibility criteria under which a sponsor may seek the "Barrier to Innovation" waiver.

Use of the PDUFA "barrier to innovation" waiver provision in the case of two applications for a combination product is appropriate. However, PhRMA disagrees with limiting this provision only to those situations in which FDA requires two applications. A sponsor who chooses to submit two applications should not be forced to forfeit any applicable waiver provided under the PDUFA "barrier to innovation."

Combination products incorporating cutting edge, innovative technologies submitted under two applications do not contain any more data or information than when submitted under a single application where consultation with another Center is a necessary component of the submission review. Regardless of who decides that two separate applications represent the most appropriate regulatory approach, eligibility for waivers should be the same. The decision to grant a waiver should be based on the innovative merits of the product, not which party determined that submission of two applications is appropriate for the combination product.

PhRMA disagrees with FDA's narrow interpretation of innovation for the purposes of granting a "Barrier to Innovation" waiver. FDA has based its interpretation on the eligibility of a product for

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expedited or priority review (see Footnote 14 of the Guidance). However, PhRMA believes that for the purposes of assessing User Fees, criteria *other* than those used for review timelines should be considered. Particularly in the era of the Critical Path Initiative, where the term innovation is applied to all manner of pre-marketing development techniques (i.e., use of biomarkers, pharmacogenomics, etc.), broader criteria for a determination of "innovative" should be applied here. In addition, not all innovative combination products are designed to offer clinical benefit. Instead, they may be designed to offer other significant benefits such as economics, convenience and usability. PhRMA recommends that FDA expand its consideration of innovations to include these criteria.

PhRMA trusts that these comments are useful to FDA as the Agency moves forward to finalize this draft Guidance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alan Goldhammer". The signature is written in dark ink on a light-colored background.