SEPRACOR

February 23, 2007

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

Re: Prescription Drug User Fee Act
[Docket No. 2007N-0005]

Dear Sir/Madam:

The following comments to Docket No. 2007N-0005 are submitted on behalf of Sepracor Inc. Sepracor is a research-based pharmaceutical company of nearly 2,500 employees with corporate headquarters located in Marlborough, Massachusetts.

We are supportive of the goals of PDUFA IV and the new initiatives outlined by the Agency in the January 16, 2007 Federal Register. A key feature of the PDUFA re-authorization proposal is additional emphasis on the safety of marketed products, and in this regard we believe that the intended outcomes, to an important degree, will depend upon the Agency making an increased commitment to timely and thorough communications and meetings with sponsors. We believe that the Agency proposal does not adequately address this need, and we are submitting this comment to encourage the Agency to consider this issue further.

In particular, we note that the principal new task to which the Agency is committing, with respect to meetings with sponsors, is the issuance of a new guidance on End-of-Phase II meetings (item II.B.1.b.4. in the FR announcement). While this will be important, we encourage the Agency to set additional, public goals with respect to meetings:

1. PDUFA IV Should Establish a Better System for Post-Approval Meetings with Sponsors

   The current schema for post-approval meetings generally revolves around the need to discuss further clinical development and CMC issues, such as supplemental or new indications, new label populations, manufacturing or testing changes, etc. As these meetings usually involve a pending supplemental NDA submission, PDUFA meeting goals usually apply, and a sponsor can generally (but certainly not always) obtain a meeting within a reasonable timeframe. Industry recognizes the extraordinary challenges that review divisions face in accommodating such meetings given the resource constraints that exist. Nevertheless, we should mutually anticipate that comprehensive management of emergent or potential safety concerns for marketed products, and the associated preparation of communications to disseminate new or revised risk information to physicians and patients, will require very timely meetings between the Agency and sponsors. Such meetings do not necessarily fall

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into the current NDA supplement-oriented schema, and in our experience are very difficult to obtain. Yet, such meetings are certainly as important as meetings related to pre-approval issues.

Specifically, we note that the Agency's proposal to amend the statute to permit PDUFA fees to be used to assess safety matters irrespective of a product's approval date is silent on how such resources might be applied to assure that timely communications are held with sponsors. Sponsors have a critically important role in facilitating scientifically-sound regulatory decision making throughout a product's lifecycle.

Therefore, we propose that PDUFA IV identify a specific category of post-approval meetings related to the review and management of safety issues, so as to provide sponsors with an opportunity to formally discuss such matters with the agency on a timely basis. A system of prioritization similar to that used for pre-approval meetings would be appropriate, and we also propose that the Agency accept performance goals for such meetings (as was the case for PDUFA II), e.g., 90% of such safety meetings are granted per the sponsor's request. We propose that the Agency concomitantly develop a specific guidance document in this regard. Essentially, we believe that the Agency's application of additional resources to the management of post-approval safety issues should not fail to consider the need for some additional resources to be applied, in a formal manner, to assuring and facilitating communications with sponsors on such issues.

2. PDUFA IV Guidance Goals Should be Broader with Respect to Meetings with Sponsors

The planned guidance document on End-of-Phase II meetings will be beneficial and is welcome. We anticipate that this guidance will be complementary to the current guidance, "Formal Meetings with Sponsors and Applicants for PDUFA Products," and that its planned issuance reflects the need for more specificity with respect to key milestone meetings. We encourage the Agency to consider developing additional guidances for key milestone meetings, such as pre-IND and pre-NDA meetings, during this next PDUFA cycle. Each such meeting has a critical purpose and contributes to the Agency's stated intention of guiding industry towards efficient use of development resources.

We appreciate this opportunity to provide comment to the Agency on the proposed re-authorization of PDUFA.

Sincerely,

Stewart H. Mueller
Senior Vice President
Regulatory Affairs and Quality Assurance