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Global Research & Development

July 24, 2003

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

Re: FDA Docket No. 2003D-228
Draft Guidance for Industry on Continuous Marketing Applications: Pilot 1-Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act

FDA Docket No. 2003D-0229
Draft Guidance for Industry on Continuous Marketing Applications: Pilot 2-Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's draft guidance regarding "Continuous Marketing Applications" published in the Federal Register on June 17, 2003. These Pilot programs are designed to examine whether providing early review of selected applications and additional feedback and advice to Sponsors during the drug development process can further shorten drug development and review times. Comments on the draft guidance are provided as the following:

Pilot 1- Reviewable Units for Fast Track Products under PDUFA (FDA Docket No. 2003D-228)

III. Pilot 1 Implementation

B. Definition of Reviewable Units

As outlined in the draft guidance, optimally the Agency would like to receive reviewable units (RUs) as complete technical sections of an NDA/BLA. As such, the Pilot's usefulness would be limited, as it may not facilitate the review of critical parts of rate-limiting sections of an application. These sections tend to be either clinical or CMC. The draft guidance suggests a Clinical Section RU should be the complete technical section, with no consideration of other possible Clinical RUs. If it were permissible to have a pivotal clinical study stand alone as a RU, this would provide more flexibility and would better facilitate rapid drug development and approval.

The draft guidance does offer some flexibility for defining RUs in several areas, and this is encouraging. However, some Divisions tend to exercise more flexibility than others in their

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approach to any regulatory review. We are concerned that there will be flexibility with some Divisions while others will accept only complete technical sections. How will CDER monitor the difference between review Divisions to ensure the differences in the various Divisions do not undermine the success of the Pilot program. We would like to see more consistency built into this Pilot without sacrificing its flexibility.

It is unclear why the Pilot proposes limiting the number of RUs per application to four. The draft guidance discusses six application subsections for possible RU submissions (CMC, P/T, Clinical Pharmacology and Biopharmaceutics, Microbiology, Clinical, and Statistical). As review resources for each of these six areas do not appear to overlap, we request the Agency consider accepting a RU from each of the areas.

C. Process for Reviewable Units

The guidance provides for discussion of a plan for submission of the RUs either during the End-of-Phase, pre-NDA/BLA meeting or at an additional meeting. If this discussion is held during a "non-entitled" meeting, the same timeframes as a Type B meeting should apply. The current meeting management goals do not provide for an RU submission plan meeting as Type B if not held under the EOP2 or pre-NDA/BLA.

D. Pilot 1 Timeline and Evaluation

The draft guidance states the earliest date for the implementation of Pilot 1 is October 1, 2003, if the guidance has been finalized, or later, when the final guidance becomes available. The Pilot will continue through September 2007. An independent consultant evaluating the Pilot shall provide the Commissioner with a preliminary report by September 30, 2006, with a final report by September 30, 2007.

The CMA Pilots were developed under PDUFA III (June 12, 2002) as a means to further shorten drug development and review times. PDUFA will next be reauthorized in 2006, thus feedback on the CMA Pilots will not be available for discussion during the PDUFA reauthorization process. We encourage the Agency to re-consider the timing of the consultant report, with a goal of having at least preliminary feedback on the Pilots available no later than the end of 2005.

When preparing the report on the Pilots, the applicant's feedback on this process will be equally important for the independent consultant to consider as those comments received from the review Division staff.

Pilot 2 – Scientific Feedback and Interactions During Development of Fast Track Products under PDUFA (FDA Docket No. 2003D-0229)

III. Pilot Implementation

A. Selection of Participant Drug and Biologic Products

While PDUFA allows for one Fast Track product per review Division in CDER and CBER, it is likely that not all Divisions will be able to participate in this Pilot. (Consider that of 19 Fast Track approvals (16 NME's) since 1998, all but one approval (Somavert) has been in the area of either HIV/AIDs or oncology.) The guidance should allow for the opportunity to expand the Pilot beyond one application per Division if there are cases where the interaction would provide obvious benefits to a development program and thus patients. Alternatively, many Divisions have several therapeutic classes within their review responsibility. Consideration could also be given to providing an opportunity for one product per therapeutic class to participate in the pilot.

B. Agreement on Feedback and Interactions

The guidance provides for a "reasonable attempt" to reach agreement between the applicant and the Division. If an agreement is not reached, the Division will notify the applicant in writing that the product will not participate in Pilot 2. There should be an opportunity to formally appeal the Division decision at the Office level or higher. The guidance seems to suggest that the Division will simply select another product for the Pilot if an agreement is not reached with the original applicant.

C. Pilot 2 Evaluation, Reporting and Conclusion

Timing for evaluating Pilot 2 is the same as for Pilot 1, thus the same comments are applicable. With a preliminary report targeted for September 30, 2006, and a final report by September 30, 2007, feedback on the CMA Pilots will not be available for discussion during the next PDUFA reauthorization process. We encourage having at least preliminary feedback on the Pilots available no later than the end of 2005.

Again, when preparing a report on the Pilot, the applicant's feedback on this process will be equally important for the consultants to consider as those comments received from the review Division staff.

We thank you for the opportunity to comment on these draft guidance.

Respectfully,

Pfizer Inc.

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