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Global Research & Development

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 03D-0317
Federal Register: July 28, 2003 (Volume 68, Number 144, Page 44345-44346)
Good Review Management Principles for PDUFA Products

Dear Drs. Jenkins and Yetter:

Thank you for the opportunity to comment on the *Good Review Management Principles for PDUFA Products*. Pfizer has participated in the development and supports comments submitted by BIO and PhRMA on this draft. Additionally, Pfizer would like to emphasize the following issues.

Filing Issues

Pfizer is encouraged by the draft guidance and the opportunity for frequent interactions during the filing process. We believe appropriate use of such interactions will help to improve predictability of the filing outcome. However, we recommend that a more precise description of a *filing* issue versus a *review* issue; as well as *correctable* issues, are articulated within the guidance.

Consultants and Interdisciplinary Communication

To improve transparency of the review, FDA should proactively communicate with sponsors as to who they plan to consult regarding the sponsor's application. FDA should inform the sponsor of the timeline for interdisciplinary interactions/consultancies early in the review process. We recommend that information on consults and interdisciplinary communication (IC) is described to sponsors in the 74-day letter. We emphasize this recommendation in cases where the agency relies upon an advisory committee or one of its members. Informing sponsors early in this process may allow sponsors an opportunity to clarify an issue before it becomes rate limiting.

We believe FDA will also benefit from proactively determining the consultancies/IC necessary early in the review process. For example, the Division of Cardio/Renal may incur a substantive workload from many other divisions to review issues of QT prolongation: improved transparency, planning and preparing for peak workload, are useful to mitigate potential bottlenecks. Informing the sponsor of the timeline and plan for consulting will improve transparency. It should also help FDA to better manage the timeline for consultancies thereby optimizing the process for first-action approvals.

The final guidance should also include details regarding the process and procedures for managing risk management consults. As the interdisciplinary communication and consultations regarding risk management plans occur, sponsor's should be aware of the timeline and potential issues as early as possible.

Additionally, the draft guidance does not address means of improving the review process for complex products such as combination products that may require multiple consultancies involving different review divisions or Centers. We suggest that FDA consider establishing an internal function to ensure that applications for combination product are more effectively managed. While the Office of Combination Products is helpful for determining the responsible review Center, review of combination products would also benefit from having an oversight or coordinating body with authority to ensure that the review of combination products are effectively coordinated and their reviews are not unnecessarily extended due to being a combination.

Discipline Review (DR) Letters

Pfizer acknowledges the potential benefits of discipline review letters as a positive step for early and real-time communication between FDA and the sponsor during the review process. We believe that active use and issuance of DR letters supports an improved process of transparency and predictability of the review outcome. We also believe that complete and robust utilization of the ninety-day conference, as provided in 21 CFR Sec. 314.102 is an excellent preliminary activity prior to issuance of the DR letters and could be an early signal to a sponsor's staff to begin preparing a rapid respond to agency queries. Effective utilization of these tools is likely to improve the review process predictability.

Advisory Committee Meetings

Pfizer believes that FDA should notify sponsors as early as possible whether an advisory committee meeting will be planned by FDA. We recommend that FDA include information regarding the likelihood of an advisory committee in the 74-day letter when possible.

Additionally, we recommend that the advisory committee meeting questions the agency proposes to seek advice upon be provided to the sponsor as early as possible. There should not be ambiguity in the questions amongst FDA, the sponsor or AC members.

Respectfully submitted,

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