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Wyeth Pharmaceuticals

1074 '03 SEP 12 A11:11 Date: September 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Re: Docket No. 03D-0317, Federal Register: July 28, 2003 (Volume 68, Number 144, Page 44345-44346)

Dear Sir/Madam:

Wyeth Pharmaceuticals is submitting the following comments on the FDA's draft guidance dated July 2003 on ***Good Review Management Principles for PDUFA Products.***

Wyeth is one of the largest research-based pharmaceutical and healthcare products companies and is a leading developer, manufacturer and marketer of prescription drugs, biologicals and over the counter medications. As a member of both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Association (BIO), Wyeth has contributed input to the comments submitted by both of these organizations and we support the recommendations that the trade associations have submitted. Rather than submitting detailed comments that replicate all of the specific points outlined by PhRMA and BIO, we are providing comments on a few selected areas of concern to complement the more specific comments submitted by the two trade organizations.

Wyeth conceptually supports the FDA's initiative to develop guidance on Good Review Management Principles in accordance with Agency's PDUFA-3 performance goals. We believe that developing and implementing guidance in this important area could lead to improved efficiency, consistency and transparency in the management of the review process for new drugs and biologics. We also believe the resulting improvement in review efficiency holds promise for faster availability of safe and effective products for the patients who need them.

Despite our belief in the merits of this initiative, however, we have concerns with certain aspects of the July 2003 draft version of the guidance. Our main areas for concern are as follows:

- In order to be of real value to Agency review personnel, we strongly believe that the guidance must be more specific, especially regarding the timing of certain Agency activities during the review process (for example, communication of FDA comments on draft labeling, and discussion of proposed post-approval commitments). The draft

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guidance is too vague and subjective in many areas, with overuse of non-specific terms such as "generally recommended".

- Specific guidance should be added regarding the timing and process for labeling negotiation. We recommend that a well-managed review process should provide for initiation of the labeling negotiation process at least 30 days prior to the PDUFA goal date. This would provide a reasonable period of time for interactions between the applicant and the FDA to agree upon labeling that contains appropriate guidance to health care professionals on the safe and proper use of the product.

- The draft guidance is unnecessarily restrictive regarding the submission of amendments to an application. The overwhelming majority of amendments are submitted in direct response to FDA requests for additional information or clarification. Earlier communication of such requests in accordance with GRMPs will ordinarily result in receipt of applicant responses earlier in the first review cycle, thus allowing FDA more time to complete its review of the application before or by the PDUFA goal date.

- Text should be added to cover communications between the Agency and applicant regarding post-approval commitments. This is a critical area that can involve a very significant commitment of industry and Agency resources, and time should be planned in the review process to ensure there are meaningful interactions regarding the objectives, scope and feasibility of any proposed studies. We recommend that FDA should communicate recommendations for any proposed post-approval studies to the applicant well in advance of the PDUFA goal date (e.g., 30 days before) to allow ample time for evaluation and interaction between the applicant and the FDA regarding the merits and feasibility of the proposed commitments.

We are submitting the enclosed comments in duplicate. Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance, and trusts that the Agency will take these comments into consideration when preparing the final guidance on Good Review Management Principles.

Sincerely,

Roy J. Baranello, Jr.
Assistant Vice President,
Worldwide Regulatory Affairs