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

Re: Docket No. 99N-1852

Dear Sir/Madam;

Proposed Rule for "Postmarketing Studies for Human Drugs and Licensed Biological Products: Status Report"

I am submitting this letter on behalf of Genzyme Corporation to provide comments on the proposed rule published in the Federal Register of December 1, 1999 (64FR 67207) and as referenced above. Outlined below are our comments as well as requests for clarification of certain items that we believe are needed either prior to or at the time of publication of the final rule.

1. The proposed rule, (*Section E*) states that annual reporting of postmarketing studies should be continued "until the agency notifies the applicant, in writing, that the study commitment has been fulfilled or acknowledges that the study is either no longer feasible or no longer provides useful information". It should be clarified as to the FDA's time frame for evaluating a final study report and notifying the applicant whether or not the postmarketing commitment has been fulfilled. This may impact whether or not an applicant needs to include this information in its next annual report and significantly reduce an applicant's reporting burden for that given year.

Further, with respect to the comment above, the requirement to continue to submit status reports on terminated postmarketing drug studies until FDA considers that the study commitments have been fulfilled is too vague. The criteria by which the Agency will deem a study fulfilled should be further clarified.

2. With respect to public disclosure (*Section F*) it would be helpful to know the extent of the information to be disclosed on FDA's website and in what format. The proposed rule states that information necessary to 1) Identify an applicant or 2) To establish the status of a postmarketing study will be made public. Such information would include the study protocol, patient accrual rates, reports of unexpected (unlabeled) suspected adverse drug experiences and study results. The term "protocol" is somewhat vague in that it does not specifically spell out what information from the protocol will be provided. Will this be a PDF copy of the actual protocol, or a study summary? Will the company have the opportunity to review the information to ensure confidential data is not disclosed before it is posted on the website? Lack of clarity in this area could lead to potential issues concerning confidentiality.

More detail would also be helpful with respect to the publication of study results. In an orphan exclusivity situation, the publication of detailed study results may allow competitors to strategically re-design clinical trials in an effort to nullify another company's market exclusivity. Detailed knowledge of study results could also lead to potential disputes between competitors via negative advertising.

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3. Regarding enforcement of this proposed reporting requirement, what steps does FDA plan to take to ensure industry compliance? Recent statements (Pink Sheet, "Postmarketing Study End of Usefulness Must Be Confirmed by FDA", Dec. 6, 1999) indicate that FDA hopes to ensure compliance of postmarketing commitments through public embarrassment. That is, the public disclosure provision of the rule was added to force companies to finish postmarketing commitments. The public disclosure provision would not necessarily add any statutory "teeth" to this rule, as public disclosure of information would not always serve as an embarrassment to all applicants. Conversely, companies diligently attempting to fulfill postmarketing commitments, but faced with unforeseen obstacles, may be subject to public embarrassment unnecessarily. For example, an applicant may not meet initial study completion timelines due to low patient accrual rates, despite legitimate attempts to enroll subjects. Information posted on FDA's website regarding their failure to complete a postmarketing commitment could negatively effect the company and their ability to complete the commitment. It is important to remember that once this information is posted on the Internet there is no limit to its access or distribution.
4. Regarding the right of FDA to publicly disclose any information concerning a postmarketing study, it should be clarified that this does not apply to CMC studies. In most instances, CMC studies will not provide useful public information and in many cases, provides information that can be proprietary in nature. We can sight one such example in the Carticel approval, where we committed to submit progress reports to FDA on our development of a serum free media. It would not be appropriate for progress on that project to be made public as we consider the information proprietary.

We look forward to understanding the overall comments received on this proposed rule and trust that the above comments will be considered.

Yours faithfully,



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Senior Vice President, Regulatory Affairs

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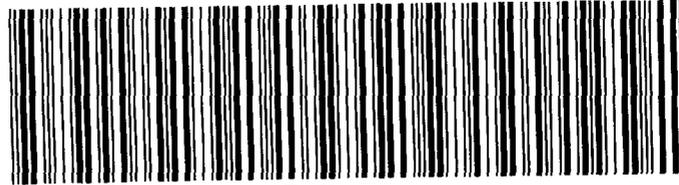
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