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Division of Dockets Management 1573 '03 AUG 14 A9:14
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: **Docket No. 2003D-0231**
Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports

13 August, 2003

Dear Sir/Madam:

Thank you for the opportunity to comment on the "Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports" published in the Federal Register on June 24, 2003. Below are Genzyme's comments for your consideration.

1. §II C states that " . . . applicants are advised to notify the Adverse Event Reporting System (AERS) electronic submission coordinator . . . prior to the first time that an ICSR is submitted electronically to the FDA." Please clarify if notification occurring prior to the first time a company submits an ICSR is sufficient, or if FDA is seeking notification for ICSRs corresponding to each drug/product.

2. In reference to the "resubmission" remarked upon in Lines 224-226, please clarify which date will be designated as the Agency received date used to comply with the 15-day reporting requirement. Please consider the following example. An ICSR was received by the Agency EDI gateway and an acknowledgement date (Date-D1) was sent back to the sponsor. However, the Agency was not able to load the ICSR into the AERS database. The sponsor then resubmitted the ICSR and received a new acknowledgement date (Date-D2) from the Agency. The Agency then attempted and successfully loaded the ICSR into the AERS database. In this scenario, which date (D1 or D2) is the official received date of this ICSR? Secondly, in this scenario, which date is the company submission date of this ICSR?

3. Line 277 references ". . . B.2.i.1 'Reaction/event as reported by the primary source....'" Please confirm that the statement refers to B.2.i.0 and not B.2.i.1 as indicated in the draft guidance.

4. § III A states that "(f)ollowup reports should provide a complete picture of the understanding of an adverse experience, rather than providing only the changes and/or updates to an ICSR." We note that there are different methods to record follow-up information. One method would entail adding additional follow-up information into a previously submitted patient narrative in a chronological order, thus documenting a complete and current narrative. Alternatively,

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follow-up information could be added to the patient narrative as a completely new and comprehensive paragraph that would include new and previously reported information. Please clarify which method would be preferable when submitting follow-up reports.

5. The draft guidance refers to presentation of the current standards for a U.S. periodic report. How does this concept relate to ICSRs that are reported as periodic submissions using the ICH PSUR format? Does this guidance apply to submission of post-marketing safety reports as described in the Tome (issued 14 March 2003) or will additional guidance be forthcoming?

Genzyme appreciates the opportunity to comment on "Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports." Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

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