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SCIENCES

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May 10, 2001

Docket Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Reference: Comments on Docket Number 01D-0056
Draft Guidance for Industry on Postmarketing Safety Reporting

Dear Sir/Madam,

Reference is made to the Federal Register Docket Number 01D-0056 dated March 12, 2001 announcing the availability of a Draft Guidance for Industry on Postmarketing Safety Reporting for Human Drug and Biological products Including Vaccines.

Comments on this Draft Guidance are hereby submitted by Gilead Sciences, Inc. in duplicate.

Gilead Sciences, Inc. appreciates the opportunity to comment on this Draft Guidance and looks forward the publication of the final version.

Please do not hesitate to contact me if I can provide any additional information. I can be reached by telephone at 303-546-7660 or by fax to 303-546-7841.

Sincerely,

Paula Opal
Regulatory Affairs Associate

01D-0056

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Comments on FDA Draft 'Guidance for Industry on Postmarketing Safety Reporting' Docket Number 01D-0056

In section V. Type of Reports, part C. Follow-up Reports, No. 2 'Reporting Considerations', lines 656 – 658:
A 15-day follow-up report should be submitted if the adverse experience is found to be serious and unexpected, even if he original report was not submitted as a 15-day report.

We have a question regarding the wording of this section:
If the original adverse event report received was not reportable, then how can there be a 15-Day Follow-up Report. Wouldn't this report be a 15-Day Alert?

In section VI. Special Reporting Situations,
part A. Scientific Literature Reports, lines 762 – 765 and part C. Foreign Reports, lines 807 – 813 (reporting experiences involving "same active moiety"):
Reports of serious, unexpected adverse experiences described in the scientific literature (or foreign reports) should be submitted for products that have the same active moiety as a product marketed in the United States. This is true even if the excipient, dosage forms, strengths, routes of administration, and indications vary.

We have two comments regarding this section:
1.) Please clarify whether these guidances are specifying two or more products sponsored by the same manufacturer, or two or more products sponsored by two (or more) different manufacturers.

2.) A company or sponsor is liable only for its own products, and therefore should only be responsible for reporting the data (efficacy, safety, etc) for its own products. There may be cases (for example lipid-based vs. conventional drugs) in which another dosage form of the same active moiety has been altered in such a way that the safety/efficacy of the product no longer retains all the characteristics of the conventional active moiety. Therefore, the safety/efficacy profile of the product may be altered in such a way that the additional reporting of active moiety information could be inaccurate. Therefore, we respectfully disagree with the guidance, and suggest to not report adverse events involving the same active moiety as the sponsored product.

Gilead Sciences, Inc
May 10, 2001

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