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

Ref: Docket No. 03D-0231, CDER/CBER 2001148. Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format -Postmarketing Periodic Adverse Drug Experience Reports.

Abbott Laboratories is pleased to have the opportunity to comment on the Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports, published in the Federal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.

We thank the Agency for their consideration of our attached comments. Should you have any questions, please contact Ivone Takenaka, Ph.D. at (847)-935-9011 or by FAX at (847) 938-3346.

Sincerely,

D. L. Sporn

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03D-0231

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Abbott

August 21, 2003

Comments on the
Draft Guidance for Industry on
Providing Regulatory Submissions in Electronic Format —
Postmarketing Periodic Adverse Drug Experience Reports

Docket No. 03D-0231

GENERAL COMMENTS

Abbott commends the Agency's effort towards the implementation of the Postmarketing Periodic Submissions in electronic format, and appreciates the current requirements described in 21CFR 314.80(c)(2) and 600.80(c)(2). However, the proposed changes on postmarketing periodic safety report submission timeframes and formats described in the recently published "Safety Reporting Requirements for Human Drugs and Biological Products" proposed rule (FR 14-Mar-2003), will greatly impact the electronic submission reporting period. To avoid confusion and too many disruptions on the current system at the expense of extra resources, Abbott recommends that the Agency delay the implementation of the electronic submission of Postmarketing Periodic Safety Adverse Drug Experience Reporting process described in this guidance, until the Safety Reporting Proposed Rule is finalized and implemented. In the meantime, in order to address the concerns below, it would be helpful to have a pilot program in place to test the efficiency of postmarketing periodic safety reporting via the electronic submission system, as recommended in this draft guidance.

Abbott suggests that the Agency provide recommendations in this guidance regarding electronic submission of a report that has no Individual Case Safety Report (ICSR). Furthermore, the guidance needs to address reports for applications that have no cases to be reported during that submission timeframe.

SPECIFIC COMMENTS

II. General Issues

A. Parts of a Postmarketing Periodic Adverse Drug Experience Report

For the convenience of the safety reviewer, it is current practice to include the approved package insert (PI) with the Postmarketing Periodic Report paper submission. If this practice is to be continued for the electronic submission, please clarify whether the PI should be submitted as a pdf file. Furthermore, please confirm that the PI should be included in the Descriptive Information.

C. Notification of Initial Electronic Submission

Lines 91-98
It is stated in this guidance *"In the Expedited Safety Reports Guidance, applicants are advised to notify the Adverse Event Reporting System (AERS) electronic submission*

coordinator at ... prior to the first time that an ICSR is submitted electronically to the FDA. This applies to all ICSRs, whether expedited or periodic."

Notifying FDA AERS electronic submission coordinator prior to first time submission of all ICSRs, whether expedited or periodic, is confusing and problematic. Abbott recommends that the requirement of prior notifications to first time electronic submission of an ICSR be removed and that the notification would be automatically done as soon as the ICSR is submitted electronically via the Gateway. FDA should set up an automatic electronic reply system containing all pertinent information that should apply to all subsequent and future reports submitted to that initial submission.

D. Sending in the Submission

There are instances that will require mixed electronic and paper submissions, e.g. when the gateway is down, or when the initial case was sent in paper and followup was sent electronically. The guidance should address the inspection and audit requirements on retention of submissions that are mixed electronic and paper submissions, e.g., whether it is necessary to retain hardcopies of reports submitted on CD-ROM or a copy of the CD-ROM would suffice. Abbott recommends that for these purposes, the reports should be retained in whichever media or form the information is originally submitted to FDA in order to avoid any corruption of the original information due to exchange of media format, software, printer settings, e.g., change in fonts.

E. Notification of Receipt of Reports by the FDA

The recommendations described in this section in regard to the electronic system not being functional may cause confusion and may jeopardize a company's compliance. Contacting the electronic submission coordinator when receipts are not received within 24hrs is problematic, e.g. when the report is submitted on Friday. Further, the guidance states that when ICSRs are sent on electronic media, companies will be contacted within three days of receipt if there is a problem in loading cases onto AERS. This timeline could potentially affect compliance rates industry wide. There could potentially be long delays if we cannot determine why and which ICSRs have not loaded into FDA's AERS database.

Abbott recommends that FDA set up an automatic reply system that immediately notifies the reporter that the transmission did not go through due to problems in the gateway/electronic system, so firms can choose other ways to notify the Agency and promptly take the appropriate action.

III. Organizing the Electronic Submission

One of the important objectives of the proposed changes described in the Safety Reporting Requirements Proposed Rule of March 14, 2003 is to further global harmonization of safety reporting. However, under this section, the guidance recommends the use of an Authorization/Application and Identification numbering formats that diverge from ICH E2B/E2BM guidelines. Abbott recommends that the Agency revise this section to be compliant with already accepted ICH guidelines.

Finally, the information in Table 1 does not clarify the requirements. A more helpful alternative is to outline a sample file directory structure.

Typographical errors
Line 133 – dockt should be docket
Line 277 - B.2.i.1 should be B.2.i.0