

G. *All Manufacturers*, located on the back page of the form.

To be considered “readable” by FDA, the computer-generated facsimile should be formatted as follows.

- The facsimile should have at least a ¼ inch margin around the entire form so that information is not lost during scanning, copying, or faxing of the document. The left-hand margin may be increased up to ½ inch to permit binding (e.g., hole-punching) of the form; all other margins should continue to be at least ¼ inch.

- The data and text that is contained within the boxes should be in a font size of not less than 10 point.

- The data and text that is contained within the boxes should be in a font type that is easy to read (e.g., CG Times, Arial) and not condensed, because the form may be copied or faxed multiple times. For visual contrast, the font type that is used for the data and text should, if possible, be different than the font type used to create the FDA Form 3500A or VAERS Form.

- All data and text should be contained within each of the boxes, e.g., an “x” mark should be centered within the box, and narratives should include margins so that letters of the text are not obscured or made ambiguous by lines defining a box.

FDA would consider “appropriate identifying information” to include:

- The name of the company centered on the top of the front page;

- In the lower left hand corner of the front page, the phrase “3500A Facsimile” instead of the phrase “FDA Form 3500A (date of form [e.g., 6/93])” or the phrase “VAERS facsimile” instead of the phrase “Form VAERS-1”;

- The phrase “continued” at the end of each field that has additional information continued onto another page; and

- On each continuation page containing additional information, the page number identified as Page ____ of ____, the manufacturer report number in the upper right corner, the name of the company in the upper right corner, and the section and block number (e.g., Block B5) for each narrative entry.

This information is included in the draft guidance of 2001. Any revisions to these parameters would be included in updated versions of the guidance.

III.F.6. Other Revisions

The proposed rule would remove §§ 310.305(d)(4), 314.80(f)(4), and 600.80(f)(4). These paragraphs provide manufacturers and applicants with addresses for obtaining copies of FDA Form 3500A and instructions for

completing the form. FDA is proposing to remove these paragraphs because the addresses are provided in the draft guidance of 2001.

The proposed rule would also remove §§ 314.80(e)(2) and 600.80(e)(2). These paragraphs state that persons subject to the postmarketing safety reporting regulations must separate and clearly mark reports of adverse drug experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the person. FDA is proposing this revision because this information would be submitted to the agency in a completed FDA Form 3500A under the box for “Report source” (box G3 on FDA Form 3500A).

III.G. Patient Privacy

Current postmarketing safety reporting regulations at §§ 310.305(e), 314.80(h), and 600.80(h) state that persons subject to these requirements should not include the names and addresses of individual patients in reports and, instead, should assign a unique code number to each report, preferably not more than eight characters in length. Proposed §§ 310.305(e), 314.80(e), and 600.80(e) would amend these regulations by removing the word “number.” This proposed amendment would clarify that the code selected to identify a patient need not be limited to numbers (*i.e.*, it could contain letters or a mixture of letters and numbers).

III.H. Recordkeeping

Current postmarketing safety recordkeeping regulations at § 314.80(i) require applicants to maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to the adverse drug experiences. Under proposed § 314.80(f), FDA would amend these regulations to read:

The applicant must maintain for a period of 10 years records of all safety information pertaining to its drug product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. The applicant must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require an applicant to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

This proposed revision clarifies the type of safety records that applicants would be required to maintain for its drug products. With regard to a request for

these records by FDA, the agency would usually make such a request either in response to a suspected safety problem associated with the use of a drug or to determine a company’s compliance with the postmarketing safety reporting requirements. Under proposed § 600.80(f), the agency is proposing similar revisions to the recordkeeping requirements for licensed biological products at § 600.80(i). FDA is proposing these revisions to clarify what types of postmarketing safety reporting records must be maintained.

Current § 310.305(f)(1) requires manufacturers, packers, and distributors to maintain for a period of 10 years records of all adverse drug experiences required under § 310.305, including raw data, any correspondence relating to adverse drug experiences, and the records required to be maintained under § 310.305. FDA is proposing to amend these regulations to be consistent with the postmarketing safety recordkeeping regulations at proposed §§ 314.80(f) and 600.80(f).

III.I. Abbreviated New Drug Application (ANDA) Products

Current § 314.98 requires applicants holding an approved ANDA to comply with the postmarketing safety reporting requirements under § 314.80. The proposed amendments to § 314.80 in this rule would apply to applicants holding an approved ANDA. For postmarketing periodic safety reporting purposes, proposed § 314.98(a) would require applicants holding an approved ANDA to determine the data lock point (*i.e.*, month and day of the international birth date or any other month and day agreed by the applicant and FDA) for their periodic safety reports based on the data lock point of postmarketing periodic safety reports for other drug products containing the same drug substance (*i.e.*, innovator NDA product that is the same drug product as the ANDA product or other ANDA products with the same drug substance if the innovator NDA product is no longer on the market). Thus, postmarketing periodic safety reports from different applicants for drug products containing the same drug substance would be submitted to FDA at the same time. Applicants holding an approved ANDA may contact FDA, if necessary, for assistance in determining the data lock point for postmarketing periodic safety reports.

Proposed § 314.98(a) would also state that applicants holding an approved ANDA would determine the type of postmarketing periodic safety report that would be required to be submitted to FDA (*i.e.*, TPSR, PSUR, or IPSR)