

appropriate identifying information, and contains all the elements (*i.e.*, format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A in the identical enumerated sequence of the form. For individual case safety reports in which no suspect medical device is involved, a one-page FDA Form 3500A is acceptable.

(d) *Multiple reports.* An applicant should not include in reports under this section any SADRs that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

(e) *Patient privacy.* The names and addresses of individual patients should not be included in reports under this section; instead, the applicant and its contractors should assign a unique code to each report, preferably not more than eight characters (*i.e.*, numbers and/or letters) in length. The name of the reporter from whom the information was received should be included. Names of patients, individual reporters, health care professionals, hospitals, and geographic identifiers in safety reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

(f) *Recordkeeping.* Each 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. Each 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.

(g) *Written procedures.* Each applicant must develop and maintain written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing safety information to FDA.

(h) *Withdrawal of approval.* If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus,

prohibit continued marketing of the drug product that is the subject of the application.

(i) *Disclaimer.* A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an SADR. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an SADR.

8. Section 314.81 is amended by removing paragraph (b)(2)(v), by redesignating paragraphs (b)(2)(vi) through (b)(2)(ix) as paragraphs (b)(2)(v) through (b)(2)(viii), respectively, and by revising paragraph (b)(2)(i) and newly redesignated paragraph (b)(2)(v) to read as follows:

§ 314.81 Other postmarketing reports.

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(b) * * *

(2) * * *

(i) *Summary.* A brief summary of significant new information from the previous year that might affect the effectiveness of the drug product or the sections of the drug product labeling that are not related to safety. The report must also contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit an efficacy labeling supplement or initiate a new study. The summary must briefly state whether supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated.

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(v) *Clinical data.* (A) Published clinical trials of the drug (or abstracts of them), including clinical trials on effectiveness; clinical trials on new uses; and biopharmaceutic, pharmacokinetic, and clinical pharmacology studies conducted by or otherwise obtained by the applicant. Review articles, papers describing safety related information or the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(B) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by,

the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(C) Analysis of available efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population must be included.

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9. Section 314.98 is amended in paragraph (a) by adding the abbreviation "(ANDA)" after the phrase "abbreviated new drug application", by removing the citation "§ 314.94" and by adding in its place the phrase "section 505(j) of the Act", by removing the phrase "adverse drug experiences" and by adding in its place the phrase "suspected adverse drug reactions", and by adding two sentences to the end of the paragraph; and in paragraph (b) by removing the phrase "Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857" and by adding in its place the word "FDA" to read as follows:

§ 314.98 Postmarketing reports.

(a) * * * For purposes of postmarketing periodic safety reporting, applicants must 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 new drug application (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). Applicants must determine the type of postmarketing periodic safety report required to be submitted to FDA (*i.e.*, traditional periodic safety report (TPSR), periodic safety update report (PSUR) or interim periodic safety report (IPSR)) and the frequency of submission for these reports based on the U.S. approval date of the application for the innovator NDA product.

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PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

10. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.