

physician responsible for the content and medical interpretation of the data contained within the form (*i.e.*, contact person for the company).

(v) Instead of using FDA Form 3500A (or a VAERS form for vaccines), the applicant may use a computer-generated facsimile of FDA Form 3500A (or the VAERS form for vaccines) provided that it is readable, includes appropriate identifying information, and contains all the elements (*i.e.*, format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A (or the VAERS form for vaccines) 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 SARs that occurred in clinical trials if they were previously submitted as part of the license application. If a report refers to more than one biological product marketed by an applicant, the applicant should submit the report to the license for the product listed first in the report.

(e) *Patient privacy.* For nonvaccine biological products, the names and addresses of individual patients should not be included in reports under this section; instead, the applicant, shared manufacturer and 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. For vaccine SAR reports, these data will become part of the CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

(f) *Recordkeeping.* Each applicant must maintain for a period of 10 years records of all safety information pertaining to its product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SARs 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 safety information to FDA.

(h) *Revocation of license.* If an applicant fails to establish and maintain records and make reports required under this section with respect to a licensed biological product, FDA may revoke the license for such a product in accordance with the procedures of § 601.5 of this chapter.

(i) *Exemptions.* Manufacturers of the following listed products are not required to submit safety reports under this section:

(1) Whole blood or components of whole blood. These products are subject to the reporting requirements for blood and blood components in § 606.170 of this chapter.

(2) In vitro diagnostic products, including assay systems for the detection of antibodies or antigens to retroviruses. These products are subject to the reporting requirements for devices.

(j) *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 biological product caused or contributed to an SAR. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the biological product caused or contributed to an SAR.

PART 601—LICENSING

14. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.28 [AMENDED]

15. Section 601.28 *Annual reports of postmarketing pediatric studies* is amended by removing the second sentence in paragraph (a) and the phrase "safety and" in the first sentence in paragraph (b).

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

16. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

17. Section 606.170 is revised to read as follows:

§ 606.170 Suspected adverse reaction investigation and reporting.

(a) Any reports of complaints of suspected adverse reactions (SARs), as defined in § 600.80(a) of this chapter, regarding each unit of blood or blood product arising as a result of blood collection or transfusion must be investigated promptly and thoroughly. Records of the complaint and investigation must be maintained. The collection or transfusing facility must prepare and maintain a written report of the investigation of SARs, including followup and conclusions, as part of the record for that lot or unit of final product. If it is determined that there was an SAR related to transfusion or possibly related to the collection procedure, then copies of all such reports must be forwarded to and maintained by the manufacturer or collection facility.

(b) For any serious SAR, as defined in § 600.80(a) of this chapter, except for a fatality, the facility performing the compatibility testing (if the SAR is related to transfusion) or the collecting facility (if the SAR is related to the blood collection procedure), must submit a written report to the Center for Biologics Evaluation and Research (CBER), at FDA within 45 calendar days after determination of the serious SAR. The written report must be submitted using the reporting format provided in § 600.80(c)(4) of this chapter.

(c) For an SAR that results in a fatality, the Director, Office of Compliance and Biologics Quality, at CBER must be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible. Within 7 calendar days after the fatality, the collection facility (if the fatality is related to blood collection) or the facility performing the compatibility tests (if the fatality is related to transfusion) must submit a written report to CBER, FDA, using the reporting format provided in § 600.80(c)(4) of this chapter.

(Information collection requirements approved by the Office of Management and Budget under control number 0910–0116)