II. Significance of Guidance

This guidance document represents the agency's current thinking on preclinical and clinical data and labeling for breast implants. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1354) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance at any time. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–20159 Filed 8–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0220]

Draft ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments'' dated August 2001. The draft guidance document provides licensed blood establishments, unlicensed registered blood establishments, and transfusion services with the agency's current thinking related to the requirements for biological product deviation reporting. The draft guidance document will assist blood and plasma establishments in determining when a report is required, who submits the report, the timeframe for reporting, and how to submit the report.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 13, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments'' dated August 2001 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments'' dated August 2001. This draft guidance document is intended to provide assistance to blood and plasma establishments regarding the reporting of any event associated with the manufacturing, testing, processing, packing, labeling, or storage or with the holding or distribution of blood or a blood component in which the safety, purity, or potency of a distributed product may be affected as required under §§ 600.14 and 606.171 (21 CFR 600.14 and 606.171) (65 FR 66621, November 7, 2000). The draft guidance document provides additional information regarding the regulations in § 606.171, which describe who must report, what must be included in the report, when the establishment must report, and provide that the establishment must report either electronically or by mail using a standardized reporting format. Examples of reportable and nonreportable events concerning donor suitability, product collection, component preparation, testing, labeling, quality control, and distribution are discussed. These examples may not apply to all establishments because they include deviations and unexpected events related to standard operating procedures implemented at individual establishments and may not be an

industry standard or a procedure at your facility. The draft guidance document also contains a biological product deviation reporting flowchart to aid in determining if an event is reportable.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking with regard to the reporting of biological product deviations in manufacturing by blood and plasma establishments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by November 13, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: July 6, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20157 Filed 8–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0221]

Draft ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components,'' dated August 2001. The draft guidance document provides licensed manufacturers of biological products other than blood and blood components with the agency's current thinking related to the biological product deviation reporting requirements. The draft guidance document will assist the licensed manufacturers of biological products other than blood and blood components in determining when a report is required, who submits the report, the timeframe for reporting, and how to submit the report.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 13, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components,'' dated August 2001. This draft guidance document is intended to provide assistance to licensed manufacturers of biological products other than blood and blood components regarding the reporting of any event associated with the manufacturing, testing, processing, packing, labeling, and storage, or with the holding or distribution of a biological product in which the safety, purity, or potency of a distributed product may be affected as required under § 600.14 (21 CFR 600.14) and 21 CFR 606.171 (65 FR 66621, November 7, 2000). The draft guidance document provides additional information regarding the regulations in § 600.14 which describe who must report, what must be included in the report, when the licensed manufacturer must report, and provide that the licensed manufacturer must report either electronically or by mail using a standardized reporting format. Examples of reportable and nonreportable events concerning incoming material specifications, process controls, product specifications, product testing, product labeling, quality control procedures, and product distribution are discussed. These examples may not apply to all establishments because they include deviations and unexpected events related to standard operating procedures implemented at individual establishments and may not be an industry standard or a procedure at your facility. The draft guidance document also contains a Biological Product Deviation Reporting Flowchart to aid in determining if an event is reportable.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking with regard to the reporting of biological product deviations in the licensed