Dated: August 7, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–20221 Filed 8–10–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–235]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Data Use Agreement and Information Collection Requirements, model language, and Supporting Regulations in 45 CFR, Section 5b;

Form No.: CMS–R–235 (OMB# 0938–0734);

Use: This agreement is used as a binding agreement stating conditions under which CMS will disclose and user will maintain CMS data that are protected by the Privacy Act.;

Frequency: On occasion;

Affected Public: Not-for-profit institutions;

Number of Respondents: 1,500;

Total Annual Responses: 1,500;

Total Annual Hours: 750.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's web site address at *http://www.hcfa.gov/regs/prdact95.htm*, or E-mail your request, including your address and phone number, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 17, 2001.

John P. Burke III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–20226 Filed 8–10–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4003]

Medical Devices; Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry.'' This guidance provides important preclinical, clinical, and labeling information that should be presented in an investigational device exemption (IDE), a premarket approval (PMA), or a product development protocol (PDP) application for any breast implant.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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: Samie Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

This final guidance provides important preclinical (chemistry, toxicology, and mechanical), clinical, and labeling information that should be presented in an IDE, PMA, or PDP application. The information discussed is relevant to breast implants filled with silicone gel, saline, or alternative filler intended for breast augmentation, breast reconstruction, and revision.

This final guidance serves to update the information provided in the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' (64 FR 54028, October 5, 1999). FDA received two comments. The first comment requested FDA to strengthen the language used throughout the guidance. The second comment involved points to consider with regard to the device description, preclinical testing, and clinical sections of the guidance. This update is based on our additional scientific review and analysis of published studies, reviews of breast implant applications, the comments received, and discussions and correspondence between the Center for Devices and Radiological Health's Plastic and Reconstructive Surgery Devices Branch and breast implant sponsors. Although some minor updates were made in the chemistry and toxicological sections of the guidance, the primary revisions were to the mechanical testing and clinical data sections to reflect our current thinking on these topics. Additionally, FDA expanded the labeling section to address all essential pieces of labeling. The manufacturing section of the draft guidance was deleted because FDA concluded that it did not provide necessary information and, instead, wanted the guidance to focus on preclinical, clinical, and labeling issues.

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