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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0002]

Draft Guidance for Industry and FDA Staff; Saline, Silicone Gel, and Alternative Breast Implants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Saline, Silicone Gel, and Alternative Breast Implants." This version of the draft guidance document updates preclinical, clinical, and labeling recommendations described in "Guidance for Saline, Silicone Gel, and Alternative Breast Implants" dated February 11, 2003. The update is based on the latest scientific and medical information on breast implants, and clarifies the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective. The draft guidance document contains new recommendations for manufacturers submitting applications for premarket approval of breast implants. Some of the recommendations apply to all premarket approval applications for breast implants, while others are specific to the type of implant. The draft guidance document is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

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ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Saline, Silicone Gel, and Alternative Breast Implants" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

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, ext. 139.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is revising the guidance document entitled "Saline, Silicone Gel, and Alternative Breast Implants" to clarify the type and amount of scientific data that should be submitted to allow FDA to evaluate whether these devices are safe and effective. The draft guidance document provides updated information based on the latest scientific and medical information on breast implants. The draft guidance document contains new recommendations for manufacturers submitting applications for premarket approval of breast implants. Some of the recommendations apply to all premarket approval applications for these

devices, while others are specific to silicone gel-filled, saline-filled, or alternative implants. The proposed changes are primarily to the mechanical data, clinical data, and labeling sections of the draft guidance document. In addition, a new section entitled "Modes and Causes of Rupture" has been added that describes the type of data FDA recommends a manufacturer provide to address this issue (this section replaces the previous Retrieval Study section). When final, this draft guidance document will supersede "Guidance for Saline, Silicone Gel, and Alternative Breast Implants," dated February 11, 2003.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Saline, Silicone Gel, and Alternative 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 requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Saline, Silicone Gel, and Alternative Breast Implants," you may either send a fax request to 301–443–8818 to receive a paper copy of the document, or send an e-mail request to *GWA@CDRH.FDA.GOV* to receive a paper copy or an electronic copy. Please use the document number (1239) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the draft guidance may also do so by 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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in Sections 3 through 10 of the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB No. 0910–0231). The labeling provisions addressed in Section 11 of the guidance document have been approved under OMB No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before [*insert date 90 days from date of publication in the* **Federal Register**]. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed 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. Comments

received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/7/04
January 7, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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