

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	Wamoni Owever

[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This final guidance serves to update the information provided in the draft guidance entitled "Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses" (64 FR 54028, October 5, 1999).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.

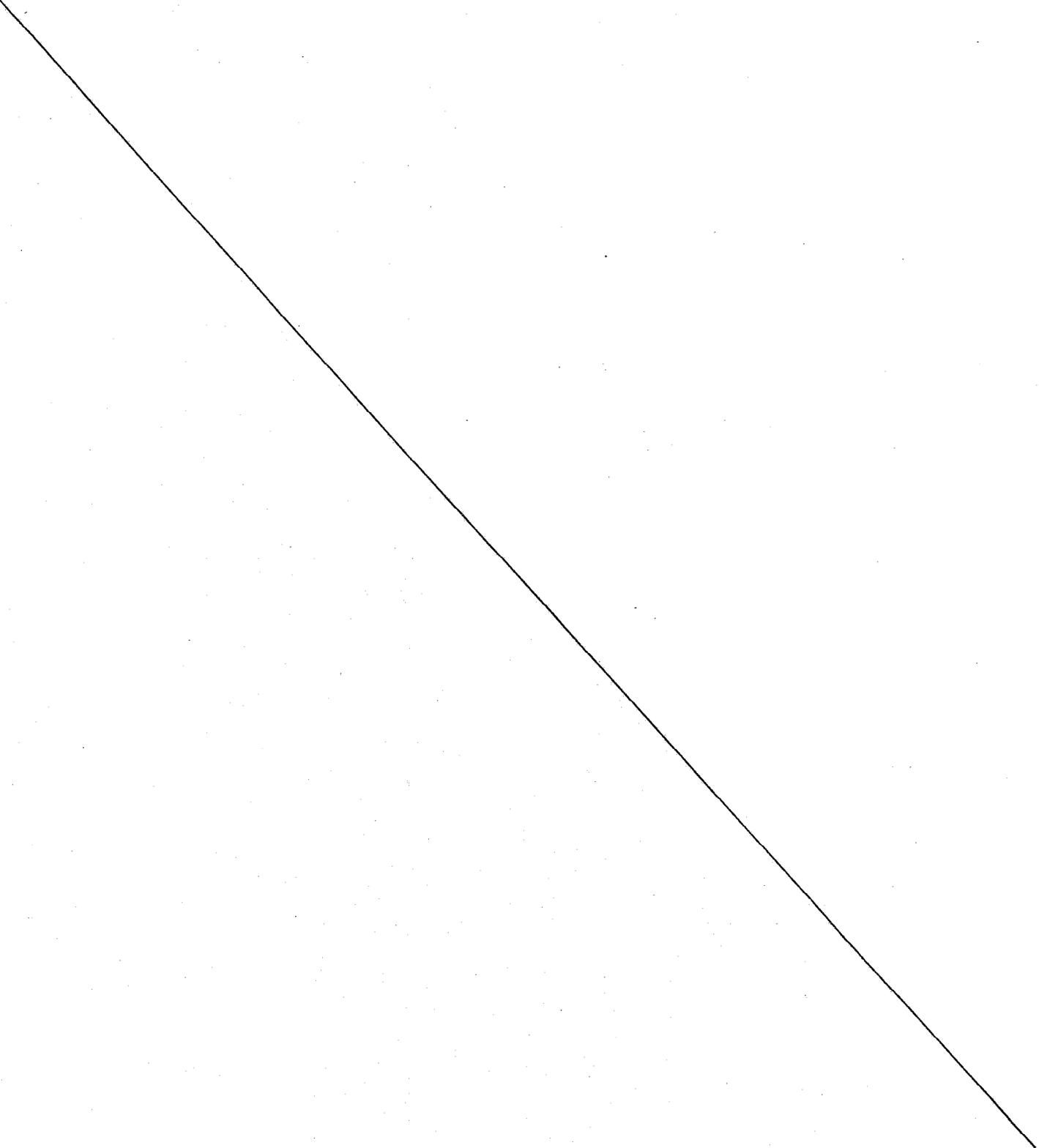
III. Electronic Access

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: 8/2/01
August 2, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director, for Regulatory Policy,
Center for Devices and Radiological Health.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Donna Oliver