

Dated: August 7, 2001.

John L. Williams,

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

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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://](http://www.hcfa.gov/regs/prdact95.htm)

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]

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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.