

By order of the Board of Governors of the Federal Reserve System, November 14, 2006.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### Notification and Obligation of the Federal Employee Antidiscrimination and Retaliation Act of 2002

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the notification and obligation of the Federal Employee Antidiscrimination and Retaliation Act of 2002 (No Fear Act). This notice is in compliance with the notification provisions set forth in Title II of the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002. The No FEAR Act requires that all Federal agencies publish an initial notice in the **Federal Register** informing Federal employees, former Federal employees, and applicants of the rights and protections available to them under Federal antidiscrimination and whistleblower protection laws.

**EFFECTIVE DATE:** This notice is effective on September 18, 2006.

**FOR FURTHER INFORMATION CONTACT:**

Arlene E. Austin, Director, Office of Equal Opportunity and Civil Rights, at (410) 786-5110 (voice), (410) 786-9549 (fax), or (410) 786-2456 (TTY); or Anita Pinder, Special Assistant, Office of Equal Opportunity and Civil Rights, at (410) 786-5493 (voice), (410) 786-9549 (fax), or (410) 786-2456 (TTY) (These are not toll free numbers).

**Special Accommodations:** This notice also is available in the following formats: Large print, audio tape, electronic file on computer disk, and on CMS's Web page <http://www.cms.hhs.gov>. Requests for this notice in an alternative format should be made to CMS's Office of Strategic Operations and Regulatory Affairs, Regulations Development Group at 1-800-743-3951 (voice), 1-866-226-1819 (TTY), or (410) 786-3064 (fax) (The fax is not a toll free number).

**Additional Information:** For additional information regarding the No FEAR Act regulations, refer to 5 CFR part 724, as well as the appropriate offices within your agency (for example, Office of Equal Opportunity and Civil Rights at 410-786-5110). Additional information regarding Federal antidiscrimination, whistleblower protection, and retaliation laws can be found at the EEOC Web site—<http://www.eeoc.gov> and the OSC Web site—<http://www.osc.gov>.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On May 15, 2002, the Congress enacted the "Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002," which is now known as the No FEAR Act. One purpose of the Act is to "require that Federal agencies be accountable for violations of antidiscrimination and whistleblower protection laws." In support of this purpose, the Congress found that "agencies cannot be run effectively if those agencies practice or tolerate discrimination." The No Fear Act also requires all agencies to provide this notice to Federal employees, former Federal employees, and applicants for Federal employment to inform employees or applicants of the rights and protections available under the Federal antidiscrimination and whistleblower protection laws.

##### II. Antidiscrimination Laws

A Federal agency cannot discriminate against an employee or applicant with respect to the terms, conditions or privileges of employment on the basis of race, color, religion, sex, national origin, age, disability, marital status or political affiliation. Discrimination on these bases is prohibited by one or more of the following statutes: 5 U.S.C. 2302(b) (1), 29 U.S.C. 206(d), 29 U.S.C. 631, 29 U.S.C. 633a, 29 U.S.C. 791, and 42 U.S.C. 2000e-16. If you believe that you have been the victim of unlawful discrimination on the basis of race, color, religion, sex, national origin, or disability, you must contact an Equal Employment Opportunity (EEO) counselor within 45 calendar days of the alleged discriminatory action, or, in the case of a personnel action, within 45 calendar days of the effective date of the action, before you can file a formal complaint of discrimination with this Agency. See, for example, 29 CFR 1614. If you believe that you have been the victim of unlawful discrimination on the basis of age, you must either contact an EEO counselor as noted above or give notice of intent to sue to the Equal Employment Opportunity Commission

(EEOC) within 180 calendar days of the alleged discriminatory action. If you are alleging discrimination based on marital status or political affiliation, you may file a written complaint with the U.S. Office of Special Counsel (OSC) (see contact information below). In the alternative (or in some cases, in addition), you may pursue a discrimination complaint by filing a grievance through this Agency's administrative or negotiated grievance procedures, if such procedures apply and are available.

##### III. Whistleblower Protection Laws

A Federal employee who has authority with respect to personnel actions must not take action against an employee or applicant because of disclosure of information by that individual that is reasonably believed to evidence violations of law, rule, or regulation; gross mismanagement; gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety, unless disclosure of the information is specifically prohibited by law and the information is specifically required by Executive order to be kept secret in the interest of national defense or the conduct of foreign affairs. Retaliation against an employee or applicant for making a protected disclosure is prohibited by 5 U.S.C. 2302(b)(8). If you believe that you have been the victim of whistleblower retaliation, you may file a written complaint (Form OSC-11) with the U.S. Office of Special Counsel at 1730 M Street NW., Suite 218, Washington, DC 20036-4505 or online through the OSC Web site—<http://www.osc.gov>.

##### IV. Retaliation for Engaging in Protected Activity

A Federal agency cannot retaliate against an employee or applicant because that individual exercises his or her rights under any of the Federal antidiscrimination or whistleblower protection laws listed above. If you believe that you are the victim of retaliation for engaging in protected activity, you must follow, as appropriate, the procedures described in the Antidiscrimination Laws and Whistleblower Protection Laws sections or, if applicable, the administrative or negotiated grievance procedures in order to pursue any legal remedy.

##### V. Disciplinary Actions

Under the existing laws, each agency retains the right, where appropriate, to discipline a Federal employee for conduct that is inconsistent with Federal Antidiscrimination and

<sup>62</sup> Network diversity supplemental charge of \$1,000 a month may apply in addition to these fees.

Whistleblower Protection Laws up to and including removal. If OSC has initiated an investigation under 5 U.S.C. 1214, however, according to 5 U.S.C. 1214(f), agencies must seek approval from the Special Counsel to discipline employees for, among other activities, engaging in prohibited retaliation. Nothing in the No FEAR Act alters existing laws or permits an agency to take unfounded disciplinary action against a Federal employee or to violate the procedural rights of a Federal employee who has been accused of discrimination.

## VI. Existing Rights Unchanged

Pursuant to section 205 of the No FEAR Act, neither the Act nor this notice creates, expands, or reduces any rights otherwise available to any employee, former employee, or applicant under the laws of the United States, including the provisions of law specified in 5 U.S.C. 2302(d).

**Authority:** Title II of the No FEAR Act, Public Law 107-174; 5 CFR Part 724.

Dated: November 17, 2006.

**Leslie Norwalk,**

*Acting Administrator.*

[FR Doc. 06-9361 Filed 11-17-06; 4:32 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0002]

### Guidance for Industry and Food and Drug Administration 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 guidance entitled "Saline, Silicone Gel, and Alternative Breast Implants." This version of the guidance document updates preclinical, clinical, and labeling recommendations described in "Guidance for Saline, Silicone Gel, and Alternative Breast Implants," dated January 13, 2004. 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.

**DATES:** Submit written or electronic comments on this guidance at any time.

General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies 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, 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 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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:** Nada Hanafi, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 144.

### SUPPLEMENTARY INFORMATION:

#### I. Background

On January 13, 2004, FDA issued a draft 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 comment period closed on April 12, 2004. FDA received over 50 comments. FDA is now issuing a finalized update to this guidance document that reflects the latest scientific and medical thinking pertaining to breast implants, and is based on the April 2005 General and Restorative Devices Panel meeting. FDA's review of two premarket approval applications for silicone gel-filled breast implants, and comments received on the 2004 draft guidance document. The primary changes to the guidance document since the 2004 draft version are to the Mechanical Data, Device Explant Analyses (formerly Modes and Causes of Rupture), and Core Study Clinical Data sections. FDA also combined the former two clinical sections. Some of the recommendations in this guidance document apply to all premarket approval applications for these devices, while others are specific

to a type of breast implant (i.e., silicone gel-filled, saline-filled, or alternative). This guidance document supercedes "Guidance for Saline, Silicone Gel, and Alternative Breast Implants," dated February 11, 2003.

#### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Saline, Silicone Gel, and Alternative Breast Implants," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1239 to identify the guidance you are requesting.

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 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 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the