DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0007]

Silicone Inflatable Breast Prostheses; Information for Women Considering Saline-Filled Breast Implants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a patient risk information sheet entitled ''Information for Women Considering Saline-filled Breast Implants.'' The purpose of this information sheet is to provide prospective patients with information about the possible risks involved with silicone inflatable breast prostheses (saline-filled breast implants).

ADDRESSES: Submit written requests for single copies of the information sheet entitled ''Information for Women Considering Saline-filled Breast Implants'' to the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. ''Information for Women Considering Saline-filled Breast Implants'' is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ–84), 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION: Saline-filled breast implants were already on the market when FDA was given the authority to regulate medical devices. After passage of the Medical Device Amendments of 1976, FDA classified this device into class III (premarket approval). Under a ''grandfather'' clause, manufacturers were permitted to continue marketing class III devices already on the market, with the understanding that at some time in the future FDA would require them to submit preclinical and clinical data showing that their devices are both safe and effective. FDA believes that it is important for prospective recipients of saline-filled breast implants to know that FDA has not yet seen or evaluated preclinical information and clinical trials on these devices. The agency believes that patients should receive information about the possible risks involved before surgery so that they have an opportunity to review the material and discuss it with their doctor. Each woman must decide with her doctor whether she is willing to accept the risks in order to achieve the expected benefits. FDA believes that this decision should be an informed one.

FDA issued a notice to promote the dissemination of information on risks associated with saline-filled breast implants in the **Federal Register** of September 26, 1991 (56 FR 49098). FDA stated in that notice that it would regard saline implants as misbranded under the Federal Food, Drug, and Cosmetic Act (the act) if their labeling does not provide adequate written information to patients on the risks associated with these devices. Included in the **Federal Register** notice was a suggested patient risk information sheet.

Subsequently, in December 1994, FDA solicited comments from health professional groups, consumer organizations, and manufacturers on updating the patient risk information sheet. FDA has sent the updated risk information sheet to the two manufacturers of saline-filled breast implants, Mentor H/S and McGhan Medical, so they can provide it to physicians who perform breast implant surgery. It is the responsibility of these physicians to provide the information sheet to prospective patients before they have decided on surgery so they can read, consider, and discuss the current information before deciding whether to have the surgery.

To ensure that patients receive the revised patient information, these two manufacturers have agreed to send a ''Dear Doctor'' letter to their physician customers, including a copy of the revised patient risk information sheet, to remind them of the importance of providing this information to all prospective patients. Written confirmation from the physicians that they agree to disseminate the revised patient information will be requested. The manufacturers also agreed to ask the American Society for Plastic and Reconstructive Surgeons to include in their next newsletter an article advising their members of the updated patient information, and reminding them of their responsibility to provide this information to all prospective patients. Lastly, the manufacturers are to ensure that all saline breast implants shipped include the revised patient risk information sheet.

The saline-filled breast implant is currently the only device legally available for breast augmentation. For breast reconstruction, the current legal restrictions on the use of silicone gel-filled implants limit their use to those cases where the saline breast prosthesis is considered medically unsatisfactory.

Because FDA believes it is important that the information in the patient risk information sheet is available to consumers and the general public, FDA is providing the text of this sheet below and will provide single copies on request to the Division of Small Manufacturers Assistance (address above).

Information for Women Considering Saline-filled Breast Implants

Saline-filled breast implants (silicone envelopes filled with salt water) were already in use in 1976 when the Food and Drug Administration (FDA) began regulating medical devices. Under this 1976 law, manufacturers could continue selling devices already on the market (''grandfathered''). But the 1976 law made it clear that at some time in the future, FDA would require manufacturers to submit their research data showing that these products are safe and effective. Women need to know that until this call for research data occurs, laboratory, animal, and human tests on some of these ''grandfathered'' products—including saline breast implants—may not have been completed by the manufacturer or reviewed by FDA.

Women considering saline-filled breast implants for breast enlargement or reconstruction should receive the following information about implants (and, when appropriate, other options for reconstruction) before surgery is scheduled. This will allow them time to review the material and discuss possible risks and benefits with her doctor. For some women, breast implants can improve their quality of life. Some breast cancer survivors believe that getting implants has been an important part of their recovery. However, other women find external breast forms to be satisfactory. Reconstruction options include breast implants or surgery using tissue from a patient's own abdomen, back, or buttocks to form a new breast. This surgery requires sufficient fat tissue and a longer operation, and like any other procedure, it is not always successful. For each woman, whether her goal is augmentation or reconstruction, the benefits may be different. With her doctor's advice, each woman must decide whether or not she wishes to accept the possible risks in order to achieve the expected results.

Breast implant surgery presents the same general risks associated with anesthesia and any other surgery. After the surgery, there are other special risks related to saline-filled breast implants. (The manufacturer's package