FDA NEWS RELEASE

For Immediate Release: June 22, 2011
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FDA provides updated safety data on silicone gel-filled breast implants

Agency highlights information women should know when considering implants

The U.S. Food and Drug Administration released a report today updating the clinical and scientific information for silicone gel-filled breast implants, including preliminary safety data from studies conducted by the manufacturers as a condition of their November 2006 approval.

While the report confirms that silicone gel-filled breast implants are safe and effective when used as intended, women should fully understand the risks prior to considering silicone gel-filled breast implants for breast augmentation or reconstruction.

Based on the report, women should know:

- Breast implants are not lifetime devices. The longer a woman has silicone gel-filled breast implants, the more likely she is to experience complications. One in 5 patients who received implants for breast augmentation will need them removed within 10 years of implantation. For patients who received implants for breast reconstruction, as many as 1 in 2 will require removal 10 years after implantation.

- The most frequently observed complications and outcomes are capsular contracture (hardening of the area around the implant), reoperation (additional surgeries) and implant removal. Other common complications include implant rupture, wrinkling, asymmetry, scarring, pain, and infection.

- The complications that existed for women receiving breast implants at the time of approval are similar to the complications observed today.

- Preliminary data do not indicate that silicone gel-filled breast implants cause breast cancer, reproductive problems or connective tissue disease, such as rheumatoid arthritis. However, in order to rule out these and other rare complications, studies would need to enroll more women and be longer than those conducted thus far.

The report includes preliminary safety data from post-approval studies conducted by each of the two breast implant manufacturers (Allergan and Mentor), a summary and analysis of adverse events received over the years by the FDA, and a comprehensive review and analysis of recent scientific publications that discuss the safety and effectiveness of silicone gel-filled breast implants. FDA approved silicone gel-filled breast implants in November 2006 for breast augmentation in women over age 22 and for breast reconstruction in all women.

As a condition of approval, the FDA required each of the two companies to conduct six post-approval studies to characterize the long-term performance and safety of the devices.

Both manufacturers have communicated to the FDA the difficulties in following women who have received silicone gel-filled breast implants. The FDA is working with Allergan and Mentor to address those challenges and increase patient participation and follow-up.

"The FDA will continue to monitor and collect safety and performance information on silicone gel-filled breast implants, but it is important that women with breast implants see their health care providers if they experience any symptoms," Jeffrey Shuren, M.D., J.D., director of FDA's Center for Devices and Radiological Health. "Women who have enrolled in studies should continue to participate so that we may better understand the long-term performance of these implants and identify any potential problems."

The FDA is holding an expert advisory panel in the next few months to discuss how post-approval studies on breast implants can be more effective.

At this time, the FDA is recommending that health care professionals and women who have silicone gel-filled breast implants do the following:

- **Follow up.** Women should continue to routinely follow up with their health care professionals. This includes getting routine MRIs to detect silent rupture.

- **Be aware.** Breast implants are not lifetime devices. Breast implants are associated with significant local complications and outcomes, including capsular contracture, reoperation, removal, and implant rupture. Some women also experience breast pain, wrinkling, asymmetry, scarring and infection.

- **Pay attention to changes**. Women should notify their health care professionals if they develop any unusual symptoms. All serious side effects should be reported to the breast implant manufacturer and Medwatch, the FDA's safety information and adverse event reporting program. Report online at http://www.fda.gov/Safety/MedWatch/default.htm or by calling 800-332-1088.

- **Stay in touch.** If a woman has enrolled in a manufacturer-sponsored post-approval study, she should continue to participate. These studies are the best way to collect information about the long-term rates of complications.

The report is part of the FDA's ongoing effort to ensure that women who have or who may be considering silicone gel-filled breast implants are informed of all possible complications and outcomes. As an additional step, the agency has redesigned its website to include comprehensive information on silicone gel-filled and saline-filled breast implants (www.fda.gov/breastimplants).

For more information:

Breast Implants Home Page
www.fda.gov/breastimplants

Executive Summary: FDA/CDRH Update on the Safety of Silicone Gel-Filled Breast Implants
http://www.fda.gov/FDAgov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259866.htm

Breast Implants: Consumer Update
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm259825.htm

Breast Implants: Things to Consider
http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM259898.pdf

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