FDA approves new silicone gel-filled breast implant
Agency requires post-approval safety studies to assess rare events

The U.S. Food and Drug Administration today approved the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Gel Filled Breast Implant to increase breast size (augmentation) in women at least 22 years old and to rebuild breast tissue (reconstruction) in women of any age. Natrelle 410 implants are manufactured by Allergan, Inc.

The FDA based its approval on seven years of data from 941 women. Most complications and outcomes reflect those found in previous breast implant studies including tightening of the area around the implant (capsular contracture), re-operation, implant removal, an uneven appearance (asymmetry), and infection. In addition, investigators observed fissures (cracks) in the gel of some Natrelle 410 implants. This is a characteristic called gel fracture and is unique to this implant.

ñItôs important to remember that breast implants are not lifetime devices. Women should fully understand the risks associated with breast implants before considering augmentation or reconstruction surgery, and they should recognize that long-term monitoring is essential,ò said Jeffrey Shuren, M.D., director of the FDAôs Center for Devices and Radiological Health.

ñThe data we reviewed showed a reasonable assurance of safety and effectiveness,ò said Shuren. ñWe will be looking at the results from post-approval studies that will focus on their long-term safety and effectiveness.ò

The silicone gel in the Natrelle 410 implant contains more cross-linking compared to the silicone gel used in Allerganôs previously approved Natrelle implant. This increased cross-linking results in a silicone gel thatôs firmer. Cross-linking refers to the bonds that link one silicone chain to another. The clinical significance of this type of silicone gel is not known.

Allerganôs studies did not compare the safety and effectiveness of the Natrelle 410 implant to other previously approved silicone gel-filled breast implants on the market. Therefore, these implants cannot be directly compared to any previously FDA-approved implant.

The FDA requires that Allergan conduct a series of post-approval studies to assess long-term safety and effectiveness outcomes and the risks of rare disease. Lessons learned from previous post-approval studies on silicone gel-filled breast implants informed the design of post-approval studies for the Natrelle 410.

As a condition of approval for the Natrelle 410 breast implants, Allergan must:

- Continue to follow, for an additional five years, approximately 3,500 women who received the Natrelle 410 implants as part of the companyôs continued access study;
- Conduct a 10-year study of more than 2,000 women receiving Natrelle 410 silicone gel-filled implants post-approval to collect information on long-term local complications (e.g., capsular contracture, reoperation, removal of implant, implant rupture) and less common potential disease outcomes (e.g., rheumatoid arthritis, breast and lung cancer, reproductive complications);
- Conduct five case control studies to evaluate the possible association between the Natrelle 410 implants, as well as other silicone gel-filled breast implants, and five rare diseasesð rare connective tissue disease, neurological disease, brain cancer, cervical/vulvar cancer and lymphoma;

- Evaluate womenôs perceptions of the patient labeling; and
- Analyze the Natrelle 410 implants that are removed from patients and returned to the manufacturer.

Silicone gel-filled breast implants are medical devices implanted under the breast tissue or under the chest muscle for breast augmentation or reconstruction. These implants have a silicone outer shell that is filled with silicone gel. They come in different sizes and styles. They have either smooth or textured shells.

Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

With todayôs approval, there are now four FDA-approved silicone gel-filled breast implant products available in the U.S. manufactured by three companies: Allergan, Mentor, and Sientra.

Allergan Inc. is based in Irvine, Calif.