FDA Approves New Silicone-Gel Breast Implant

The Associated Press

The Food and Drug Administration said Wednesday that it approved a new type of breast implant from Allergan for women 22 years and older.

The FDA said the Natrelle 410 implant contains silicone gel that is firmer than Allergan's older Natrelle models. Allergan's studies did not compare the safety of the new implant with that of older implants.

The FDA has wrestled with the safety of silicone-gel implants for more than 20 years. In 1992 the agency banned the implants amid fears they could cause cancer, lupus and other illnesses. But when research ruled out most of the disease concerns, regulators allowed the implants back on the market in 2006.

Since then the FDA has required manufacturers to track any complications experienced by women who receive the implants. The most recent data from Allergan and J&J confirm that the devices can rupture and often need to be replaced.

The FDA in a release Wednesday said the Natrelle 410 was studied in 941 women over a seven-year period.

"The data we reviewed showed a reasonable assurance of safety and effectiveness," said Dr. Jeffrey Shuren, the FDA's medical device director. "We will be looking at the results from post-approval studies that will focus on their long-term safety and effectiveness."

Irvine, Calif.-based Allergan sells breast implants, Botox anti-wrinkle injections and other cosmetic treatments.

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