FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants

The agency adds restrictions and approves new labeling for all approved breast implants.

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On October 27th, the U.S. Food and Drug Administration took several new actions to strengthen breast implant risk communication and help those who are considering breast implants make informed decisions.

First, the agency issued orders restricting the sale and distribution of breast implants to help ensure that patients considering breast implants are provided with adequate risk information so that they can make fully informed decisions. Additionally, the agency has approved new labeling for all legally marketed breast implants that includes a boxed warning, a patient decision checklist, updated silicone gel-filled breast implant rupture screening recommendations, a device description with a list of specific materials used in the device and a patient device card. Finally, the FDA released updated information on the status of breast implant manufacturer post-approval studies. These actions will help patients understand the risks and benefits of breast implants and make more informed decisions about their health.

“Protecting patients’ health when they are treated with a medical device is our most important priority,” said Binita Ashar, M.D., director of the Office of Surgical and Infection Control Devices in the Center for Devices and Radiological Health. “In recent years, the FDA has sought more ways to increase patients’ access to clear and understandable information about the benefits and risks of breast implants. By strengthening the safety requirements for manufacturers, the FDA is working to close information gaps for anyone who may be considering breast implant surgery. As the FDA continues to evaluate the overall effects of breast implants in patients, today’s actions help ensure that all patients receive the information they need to make well-informed decisions affecting their long-term, personal health.”

The FDA has taken a number of steps to better understand the patient perspective and address risks associated with breast implants, including convening the General and Plastic Surgery Devices Advisory Panel in 2019 to publicly discuss the long-term benefits and risks of breast implants indicated for breast augmentation and reconstruction. The meeting covered a range of important topics on breast implant safety, including characterization of breast implant associated anaplastic

large cell lymphoma (BIA-ALCL) incidence and risk factors and methods for assessing systemic symptoms referred to by patients as breast implant illness. The panel gave recommendations on these topics, including recommending that the FDA require a boxed warning in breast implant labeling and a standardized checklist as part of the informed consent process, revise the MRI screening recommendations for silent ruptures of silicone gel-filled breast implants and provide greater transparency regarding materials present in breast implants.

Following the 2019 panel meeting, the FDA issued final guidance for breast implants that recommends labeling updates, including a patient decision checklist, screening recommendations for ruptures, information about breast implant materials and a patient device card. The final guidance was issued in September 2020.

The FDA's order today restricts the sale and distribution of breast implants to only health care providers and facilities that provide information to patients utilizing the patient brochure "Patient Decision Checklist." The checklist must be reviewed with the prospective patient by the health care provider to help ensure the patient understands the risks, benefits and other information about the breast implant device. The patient must be given the opportunity to initial and sign the patient decision checklist and it must be signed by the physician implanting the device.

The FDA is requiring these restrictions based on its finding that the available information indicates such restrictions are necessary to provide a reasonable assurance of the device's safety and effectiveness. The FDA is committed to continuing to use its full authorities to ensure the post-market safety of medical products.

The new labeling approved today follows the labeling recommendations described in FDA's September 2020 guidance and was included as part of the supplemental approval applications submitted by manufacturers. The FDA orders for IDEAL IMPLANT Structured Saline Breast Implants, Mentor Saline-Filled and Spectrum Breast Implants, Inamed (now Allergan) Natrelle Saline Filled Breast Implants, Inamed (now Allergan) Natrelle Silicone Filled Breast Implants, Mentor MemoryShape Silicone Gel-Filled Breast Implants, Mentor MemoryGel Silicone Gel-Filled Breast Implants and Sientra OPUS Silicone Gel Breast Implants approve the updated labeling in addition to restricting the devices as described above. Manufacturers are asked to post the updated device labeling to their websites within the next 30 days.

Based on these approval orders, product labeling for these devices now includes a boxed warning to inform patients of significant risks of breast implants, as well as updated silicone gel-filled breast implant rupture screening recommendations, a patient decision checklist, inclusion of a description of materials used in breast implants and chemicals that can be released from breast implants and patient device cards, all of which were recommended at the March 2019 Panel Meeting. A medical device's labeling is intended to enhance, but not replace, the physician-patient discussion of the risks and benefits of breast implants that uniquely pertain to individual patients.

The post-approval study data released today furthers the FDA's commitment to transparently understanding the long-term effects of breast implants by providing status updates of all breast

implant studies, as required by the premarket approval (PMA) process.

Breast implants are designated as a Class III medical device, which includes devices that support or sustain human life, are of substantial importance in preventing impairment of human health or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated, Class III devices require PMA approval before a manufacturer can legally market their device, which is the most stringent type of device marketing application required by the FDA.

Related Information

- Breast Implants
- March 25-26, 2019: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement
- Post-approval Study Updates: IDEAL IMPLANT Structured Saline Breast Implants, Sientra OPUS Silicone Gel Breast Implants, Mentor MemoryGel Silicone Gel-Filled and MemoryShape Breast Implants (P060028 / PAS003 and P030053 / PAS008), Inamed (now Allergan) Natrelle (P020056/PAS008 and P040046/PAS003)

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