## Class 2 Recall Natrelle

See Related Information[23]

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| **Date Posted** | July 07, 2015 |
| **Recall Status[1]** | Open |
| **Recall Number** | Z-1988-2015 |
| **Recall Event ID** | 71428[24] |
| **Premarket Notification 510(K) Number** | K831566[25] |
| **Product Classification** | Sizer, Mammary, Breast Implant Volume[26] - **Product Code** MRD[27] |
| **Product** | Natrelle Re-sterilizable Breast Implant Sizer, Size: 410 cc, Style No. MSZFX410. The product is packaged in a thermoformed tray (double sterile barrier) and enclosed in a labeled carton. |
| **Code Information** | Lot # Serial # Style #: 1703043, 14124459, MSZFX410; 1708499, 14164655, MSZFX410; 1801072, 14768661, MSZFX410; 1819375, 14905528, MSZFX410; 1819377, 14911183, MSZFX410; 1819377, 14911197, MSZFX410; 1819377, 14911180, MSZFX410; 1819378, 14907262, MSZFX410; 1819378, 14907266, MSZFX410. |
| **Recalling Firm/ Manufacturer** | Allergan Inc<br>2525 Dupont Dr<br>Irvine, California 92612-1531 |
| **Manufacturer Reason for Recall** | Allergan is recalling the NATRELLE 410cc Re-Sterilizable Breast Implant Sizer because the expired product was shipped to the user level. |
| **FDA Determined Cause [2]** | PRODUCTION CONTROLS: Error in Labeling |
| **Action** | A recall letter dated 6/8/15 was sent to all customers who received the NATRELLE 410 cc Re-Sterilizable Breast Implant Sizer. The letter provides the problem identified and the action to be taken. Customers are instructed to contact GENCO Pharmaceutical Services if the recall actions on the recall letter are unclear. For product returns, customers are instructed to contact GENCO at (877) 319-8966, 7am to 5pm CST. Customers with credit/reimbursements are instructed to contact Allergan at (800) 811-4148, 7am to 5pm PST. Customers with medical inquiries are instructed to contact (800) 433-8871, option 2, 8am-5pm, PST. Customers with adverse events/product complaints are instructed to call (800) 624-4261, option 3, 8am-5pm CST. On June 12, 2015, Actavis sent follow up letters to customers to include one additional serial number. |
| **Quantity in Commerce** | 9 units |
| **Distribution** | CA, IN, MO, NJ, VA |
| **Total Product Life Cycle** | TPLC Device Report[28] |

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

**510(K) Database** 510(K)s with Product Code = MRD and Original Applicant = COX-UPHUFF INTL.[30]