UPDATE: LANNETT ISSUES VOLUNTARY NATIONWIDE RECALL OF RANITIDINE SYRUP (RANITIDINE ORAL SOLUTION, USP), 15MG/ML DUE TO AN ELEVATED LEVEL OF THE UNEXPECTED IMPURITY, N-NITROSODIMETHYLAMINE (NDMA)

November 12, 2019 – Lannett Company, Inc. today announced an update regarding its recent voluntary recall of Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/mL due to the levels of N-Nitrosodimethlamine (NDMA) found in the product, which are above the acceptable levels recently established by the FDA. Lannett is voluntarily recalling all lots within expiry of Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/mL to the retail level (Class II), which means wholesalers and distributors (direct customers of Lannett) that have affected lots of Ranitidine Syrup should contact Inmar, Lannett's returns services provider at 1 (800) 967-5952 or at rxrecalls@Inmar.com Lannett's original press release and public notification was intended to inform and notify consumers about the recall activity so that they were made aware of the event.

To provide a recap of our previous announcement on October 25, 2019: Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA.

Risk Statement: NDMA is classified as a probable human carcinogen, a substance that can cause cancer, based on laboratory testing. NDMA is also a known environmental contaminant found in water and foods, including meats, dairy and vegetables.

The product is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of GERD and treatment of endoscopically diagnosed erosive esophagitis and is packaged in bottles of 16 fluid ounces (one pint) (NDC 54838-550-80). The affected Ranitidine Syrup lots include the following:

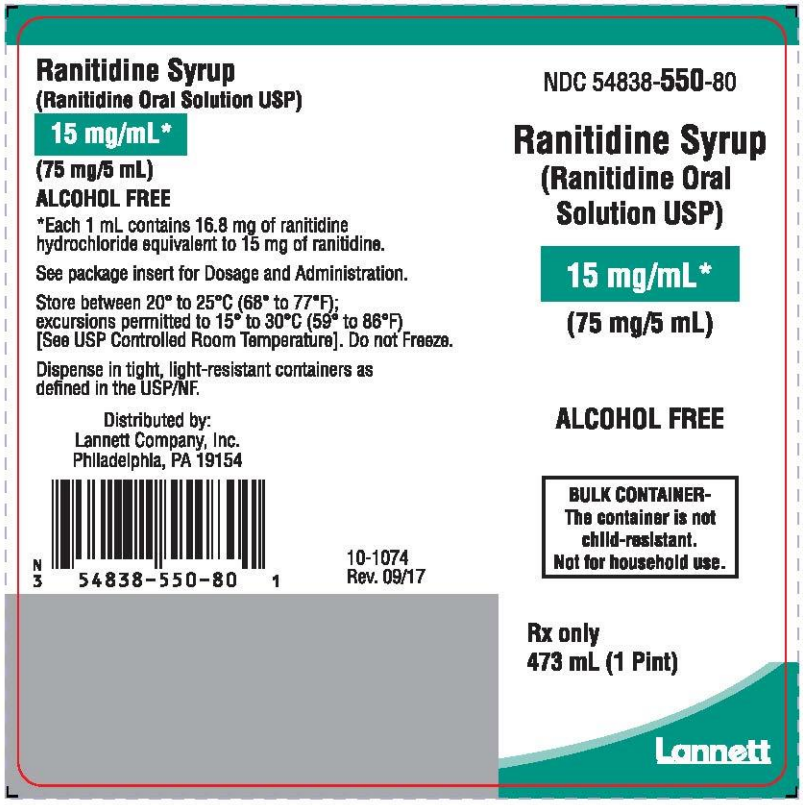
NDC Code	Batch	Expiration Date
54838-550-80	1503A	10/2019
54838-550-80	1504A	10/2019
54838-550-80	1505A	10/2019
54838-550-80	1523A	10/2019
54838-550-80	1524A	10/2019
54838-550-80	1525A	11/2019
54838-550-80	1561A	12/2019
54838-550-80	1562A	12/2019
54838-550-80	1563A	12/2019
54838-550-80	1589A	12/2019
54838-550-80	1590A	12/2019
54838-550-80	1591A	12/2019

NDC Code	Batch	Expiration Date
54838-550-80	1646A	02/2020
54838-550-80	1647A	02/2020
54838-550-80	1668A	03/2020
54838-550-80	1669A	03/2020
54838-550-80	1670A	03/2020
54838-550-80	1708A	03/2020
54838-550-80	1709A	04/2020
54838-550-80	1710A	04/2020
54838-550-80	1729A	04/2020
54838-550-80	1730A	04/2020
54838-550-80	1731A	04/2020
54838-550-80	1757A	05/2020

54838-550-80	1614A	01/2020
54838-550-80	1615A	01/2020
54838-550-80	1617A	01/2020
54838-550-80	1644A	02/2020
54838-550-80	1775A	06/2020
54838-550-80	1794A	06/2020
54838-550-80	1795A	06/2020
54838-550-80	1796A	06/2020
54838-550-80	1817A	06/2020
54838-550-80	1818A	07/2020
54838-550-80	1819A	07/2020
54838-550-80	1840A	08/2020
54838-550-80	1840B	08/2020
54838-550-80	1841A	08/2020
54838-550-80	1842A	08/2020
54838-550-80	1863A	08/2020
54838-550-80	1864A	09/2020
54838-550-80	1865A	09/2020
54838-550-80	1899A	10/2020
54838-550-80	1900A	10/2020
54838-550-80	1901A	10/2020
54838-550-80	1910A	10/2020
54838-550-80	1911A	10/2020
54838-550-80	1912A	10/2020
54838-550-80	1918A	10/2020
54838-550-80	1919A	10/2020
54838-550-80	1920A	10/2020
54838-550-80	1925A	10/2020
54838-550-80	1926A	10/2020
54838-550-80	1927A	10/2020
54838-550-80	1977A	12/2020
54838-550-80	1978A	12/2020
54838-550-80	1979A	12/2020

54838-550-80	1758A	05/2020
54838-550-80	1759A	05/2020
54838-550-80	1773A	06/2020
54838-550-80	1774A	06/2020
54838-550-80	1989A	12/2020
54838-550-80	1990A	12/2020
54838-550-80	1991A	12/2020
54838-550-80	1998A	01/2021
54838-550-80	1999A	01/2021
54838-550-80	2000A	01/2021
54838-550-80	2019A	01/2021
54838-550-80	2020A	01/2021
54838-550-80	2065A	03/2021
54838-550-80	2066A	03/2021
54838-550-80	2067A	03/2021
54838-550-80	2071A	03/2021
54838-550-80	2072A	03/2021
54838-550-80	2073A	03/2021
54838-550-80	2076A	03/2021
54838-550-80	2077A	03/2021
54838-550-80	2078A	03/2021
54838-550-80	2126A	05/2021
54838-550-80	2127A	05/2021
54838-550-80	2128A	05/2021
54838-550-80	2164A	06/2021
54838-550-80	2165A	06/2021
54838-550-80	2166A	06/2021
54838-550-80	2179A	06/2021
54838-550-80	2180A	07/2021
54838-550-80	2181A	07/2021
54838-550-80	2214A	08/2021
54838-550-80	2215A	08/2021
54838-550-80	2216A	08/2021

The product can be identified by NDC number and batch numbers provided above. Ranitidine Syrup was distributed nationwide to wholesalers/distributors.



Lannett is notifying its distributors and customers via email and via the Lannett website, and is arranging for return of all recalled products through Inmar, its returns services provider. Wholesalers and distributors (direct customers of Lannett) that have Ranitidine lots which are being recalled should contact Inmar for instructions with regard to returning any remaining stock to Lannett.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Further information can be found at www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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