October 31, 2019

COM-2019-047

Recall: Additional Voluntary Nationwide Recalls of Ranitidine

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on October 25, 2019, the U.S. Food and Drug Administration (FDA) issued additional statements notifying that Novitium Pharma and Lannett Company are recalling all their ranitidine products due to the presence of NDMA (N-nitrosodimethylamine) a probable human carcinogen. The affected lots are detailed in following table.

Table 1: Affected Products of Ranitidine

Description	Strength & Type	Pack Size	NDC
Novitium Pharma			
Ranitidine Capsules 150mg	150 mg Rx	60 ct bottle	70954-001-20
Ranitidine Capsules 300mg	300 mg Rx	100 ct bottle	70954-002-40
Ranitidine Capsules 150mg	150 mg Rx	500 ct bottle	70954-001-40
Ranitidine Capsules 300mg	300 mg Rx	30 ct bottle	70954-002-10

NDC Code	Batch	Expiration Date	NDC Code	Batch	Expiration Date
Lannett Company					
4838-550-80	1503A	10/2019	54838-550-80	1646A	02/2020
54838-550-80	1504A	10/2019	54838-550-80	1647A	02/2020

NDC Code	Batch	Expiration Date	NDC Code	Batch	Expiration Date
54838-550-80	1505A	10/2019	54838-550-80	1668A	03/2020
54838-550-80	1523A	10/2019	54838-550-80	1669A	03/2020
54838-550-80	1524A	10/2019	54838-550-80	1670A	03/2020
54838-550-80	1525A	11/2019	54838-550-80	1708A	03/2020
54838-550-80	1561A	12/2019	54838-550-80	1709A	04/2020
54838-550-80	1562A	12/2019	54838-550-80	1710A	04/2020
54838-550-80	1563A	12/2019	54838-550-80	1729A	04/2020
54838-550-80	1589A	12/2019	54838-550-80	1730A	04/2020
54838-550-80	1590A	12/2019	54838-550-80	1731A	04/2020
54838-550-80	1591A	12/2019	54838-550-80	1757A	05/2020
54838-550-80	1614A	01/2020	54838-550-80	1758A	05/2020
54838-550-80	1615A	01/2020	54838-550-80	1759A	05/2020

NDC Code	Batch	Expiration Date	NDC Code	Batch	Expiration Date
54838-550-80	1617A	01/2020	54838-550-80	1773A	06/2020
54838-550-80	1644A	02/2020	54838-550-80	1774A	06/2020
54838-550-80	1775A	06/2020	54838-550-80	1989A	12/2020
54838-550-80	1794A	06/2020	54838-550-80	1990A	12/2020
54838-550-80	1795A	06/2020	54838-550-80	1991A	12/2020
54838-550-80	1796A	06/2020	54838-550-80	1998A	01/2021
54838-550-80	1817A	06/2020	54838-550-80	1999A	01/2021
54838-550-80	1818A	07/2020	54838-550-80	2000A	01/2021
54838-550-80	1819A	07/2020	54838-550-80	2019A	01/2021
54838-550-80	1840A	08/2020	54838-550-80	2020A	01/2021
54838-550-80	1840B	08/2020	54838-550-80	2065A	03/2021
54838-550-80	1841A	08/2020	54838-550-80	2066A	03/2021

NDC Code	Batch	Expiration Date	NDC Code	Batch	Expiration Date
54838-550-80	1842A	08/2020	54838-550-80	2067A	03/2021
54838-550-80	1863A	08/2020	54838-550-80	2071A	03/2021
54838-550-80	1864A	09/2020	54838-550-80	2072A	03/2021
54838-550-80	1865A	09/2020	54838-550-80	2073A	03/2021
54838-550-80	1899A	10/2020	54838-550-80	2076A	03/2021
54838-550-80	1900A	10/2020	54838-550-80	2077A	03/2021
54838-550-80	1910A	10/2020	54838-550-80	2126A	05/2021
54838-550-80	1911A	10/2020	54838-550-80	2127A	05/2021
54838-550-80	1912A	10/2020	54838-550-80	2128A	05/2021
54838-550-80	1918A	10/2020	54838-550-80	2164A	06/2021
54838-550-80	1919A	10/2020	54838-550-80	2165A	06/2021
54838-550-80	1920A	10/2020	54838-550-80	2166A	06/2021

NDC Code	Batch	Expiration Date	NDC Code	Batch	Expiration Date
54838-550-80	1925A	10/2020	54838-550-80	2179A	06/2021
54838-550-80	1926A	10/2020	54838-550-80	2180A	07/2021
54838-550-80	1927A	10/2020	54838-550-80	2181A	07/2021
54838-550-80	1977A	12/2020	54838-550-80	2214A	08/2021
54838-550-80	1978A	12/2020	54838-550-80	2215A	08/2021
54838-550-80	1979A	12/2020	54838-550-80	2216A	08/2021

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
3. Questions regarding this recall, refer to the contact information below:
    a. **Novitium Pharma -** Consumers: Navya Jaikumar, (609) 469-5920, info@novitiumpharma.com
    b. **Lannett Company -** Consumers: (215) 333-9000, extension 4, customerservice@lannett.com

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- 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

For additional information visit:

- **Novitium Pharma:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novitium-pharma-issues-voluntary-national-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg
- **Lannett Company:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lannett-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral-solution-usp-15mgml-due

Clinical Department