Novitium Pharma Issues Voluntary National Recall of Ranitidine Hydrochloride Capsules 150mg and 300mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA)

Company Contact:

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FOR IMMEDIATE RELEASE – October 25, 2019 – East Windsor, New Jersey – Novitium Pharma LLC (Novitium) is voluntarily recalling all quantities and lots, within expiry, of Ranitidine Hydrochloride Capsules in the US to the consumer level. Ranitidine Hydrochloride Capsules are being recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA. To date, Novitium has not received any reports of adverse events related to use of the product as part of this recall.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine Hydrochloride Capsules are indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable. The affected Ranitidine Hydrochloride Capsule can be identified by NDC numbers stated on the product label.

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

Novitium will be notifying its distributors and customers via email and via the Novitium website and will arrange for return of all recalled products. Wholesalers (direct customers) will be asked to immediately stop distribution and return any stock to Novitium by contacting Cardinal Health Specialty Services and contact the retail pharmacies in their group to do the same. Pharmacies will be asked to immediately stop dispensing Novitium Ranitidine Hydrochloride Capsules and return remaining stock to Novitium by contacting Cardinal Health Specialty Services to request a recall packet.

Consumers are asked to continue taking their medication and speak to their physician or pharmacist about alternate healthcare treatment options. Consumers, desiring to return product, should contact the pharmacy from which it was purchased.

Consumers with questions regarding this recall can contact **Novitium** at: (609) 469-5920 between 8am and 5pm (Monday-Friday) or e-mail: info@novitiumpharma.com. 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.

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[1]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm[2] 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.

Ranitidine Capsules 150mg and 300mg Labeling: