COMPANY ANNOUNCEMENT

Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product

Summary

Company Announcement Date:

October 23, 2019

FDA Publish Date:

October 23, 2019

Product Type:

Drugs

Reason for Announcement:

Presence of N-Nitrosodimethylamine (NDMA)

Company Name:

Perrigo Company plc

Brand Name:

Perrigo Company plc

Product Description:

Ranitidine (all pack sizes)

Company Announcement

As a precautionary measure, Perrigo Company plc announced today that it has initiated a voluntary, worldwide product recall to the retail customer level of ranitidine (all pack sizes). The recall is being taken due to possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

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 is an over-the-counter (OTC) and prescription product indicated for the relief of heartburn associated with acid indigestion and sour stomach and prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages.

After regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall.

Perrigo has the highest commitment to consumer safety and will continue to communicate ongoing testing results with health authorities. 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.

Perrigo is notifying our retail customers by phone, email or other communication with recall notification communications to arrange for the return of all recalled 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) 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.

About Perrigo

Perrigo Company plc is dedicated to making lives better by bringing high quality and affordable selfcare products that consumers trust everywhere they are sold. The Company is a leading provider of over-the-counter health and wellness solutions that enhance individual well-being by empowering consumers to proactively prevent or treat conditions that can be self-managed. Visit Perrigo online at http://www.perrigo.com (http://www.perrigo.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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