SANDOZ A Novartis Division

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Sandoz Inc. Issues Voluntary Recall of Ranitidine Hydrochloride Capsules 150mg and 300mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA), in the Product

The affected Sandoz **Ranitidine includes 30 count, 60 count and 500 count bottles** in the following lots:

Product Name	NDC Number	Lot Nbr.	Expiration Date	Date of Manufacture
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HD1862	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9438	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9439	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9440	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HC9266	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HD1865	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HP9441	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK7994	8/31/2021	8/7/2018
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK8659	8/31/2021	8/7/2018
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD8625	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD9275	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HU2207	8/31/2020	8/24/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6676	3/31/2021	3/20/2018
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6677	3/31/2021	3/20/2018

The product can be identified by the NDC number and lot number provided above.

Sandoz Ranitidine Hydrochloride Capsules were distributed nationwide to wholesalers.

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