URGENT: DRUG RECALL

Esomeprazole Magnesium Delayed-Release Capsules USP, 20mg & 40mg

June 21, 2022

Dear Customer,

This notice is to inform you of a product recall involving:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg	90 Count	AC14299	63304-734-90	12/2022
Esomeprazole Magnesium Delayed-Release Capsules, USP 40mg	90 Count	AC14304	63304-735-90	12/2022

See enclosed product labeling.

This recall has been initiated in response to an out of specification assay test result, which was observed during routine stability testing on lot AC14299. The assay result is 112.6%, slightly higher than the upper specification limit of 110.0%. An investigation was conducted by Sun Pharma, and found that lot AC14304 may also be impacted, although no out of specification result has so far been observed.

Sun Pharma conducted a Health Hazard Evaluation (HHE) and found that the out of specification assay result is unlikely to pose any risk to patient safety. However, out of an abundance of caution, Sun Pharma has decided to voluntarily recall the aforementioned lots.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on 03/05/2021.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your retail customers and notify them at once of this product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter.

Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar, Inc.
3845 Grand Lakes Way
Suite 125
Grand Prairie, TX 75050

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-855-893-5572. Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the retail level.

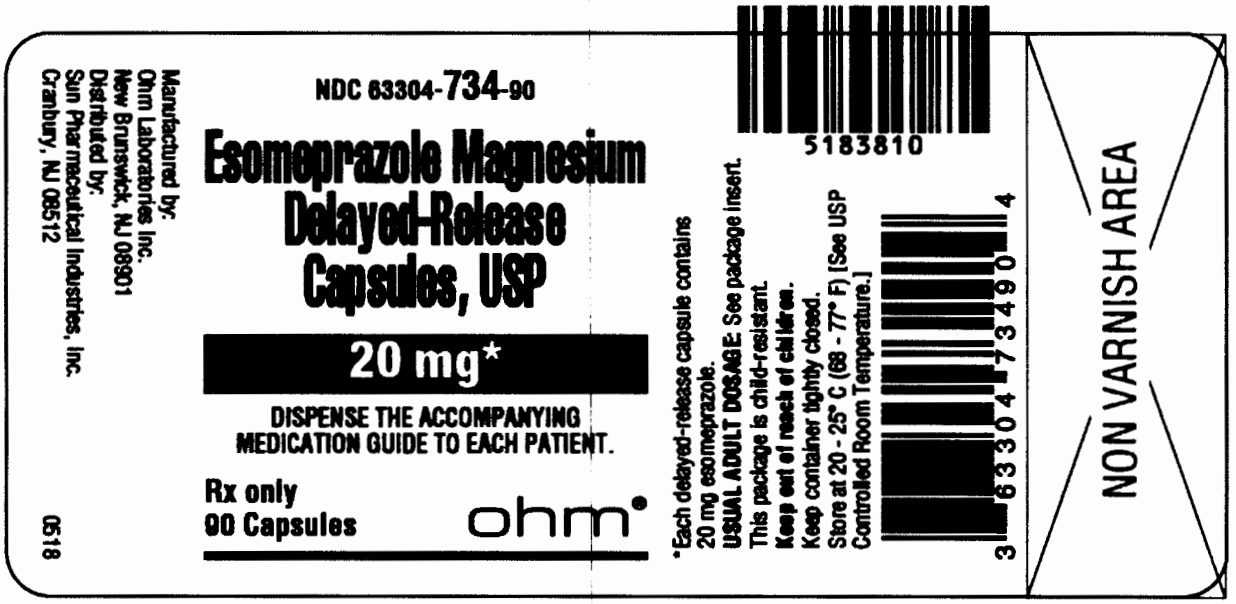
Your assistance is appreciated and necessary to prevent patient harm.

This recall is being made with the knowledge of the Food and Drug Administration.

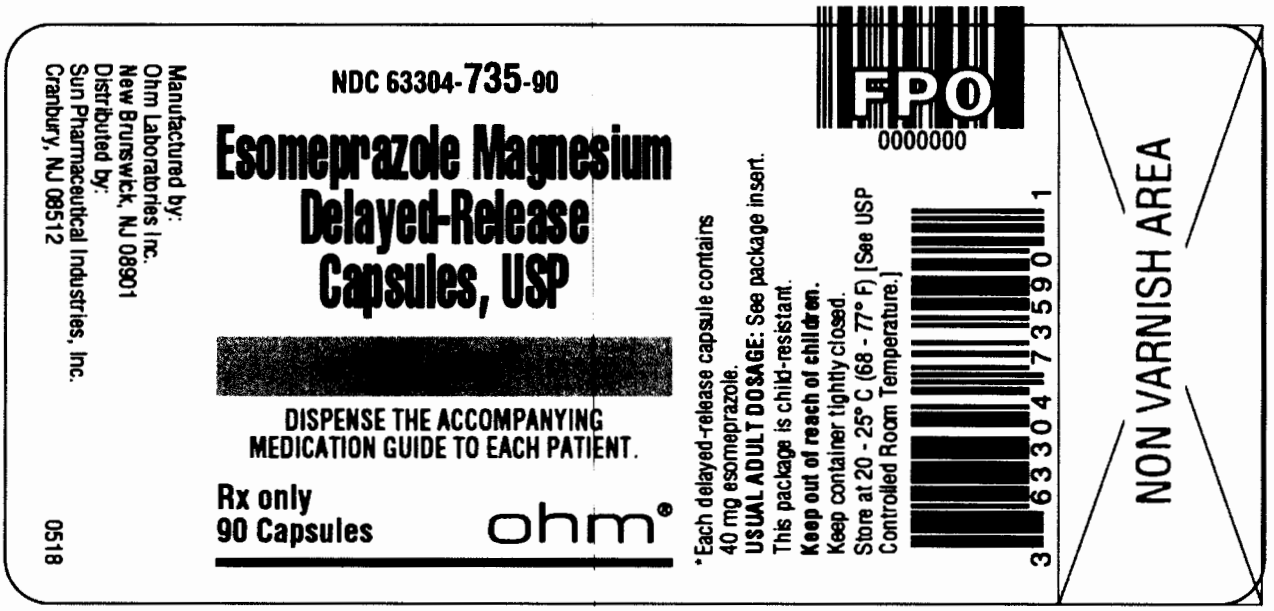
June 21, 2022

James Mullen
Sun Pharmaceutical Industries, Inc.
Manager, Cluster Quality Support

Enclosures:
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg; Bottle Labeling:



Esomeprazole Magnesium Delayed-Release Capsules, USP 40mg; Bottle Labeling:



For return of affected product, please email rxrecalls@inmar.com or call 1-855-893-5572.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg	90 Count	AC14299	63304-734-90	12/2022
Esomeprazole Magnesium Delayed-Release Capsules, USP 40mg	90 Count	AC14304	63304-735-90	12/2022

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the June 21, 2022 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units (number of full cartons) or _____ prescription packs (partial cartons).

□ Indicate disposition of recalled product:

□ returned (**specify quantity, date and method**)/held for return;

Number of Labels Required for Return to Inmar: _____

□ previously destroyed (**specify quantity, date and method**);

□ I have identified and notified my retail customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or

□ Attached is a list of wholesale customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? □ Yes □ No
If yes, please explain: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-893-5572.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Esomeprazole Magnesium Delayed-Release Capsules, USP 20mg	90 Count	AC14299	63304-735-90	12/2022
Esomeprazole Magnesium Delayed-Release Capsules, USP 40mg	90 Count	AC14304	63304-734-30	12/2022

Please check the appropriate box(es) to describe your business

- □ wholesaler/distributor
- □ grocery corporate headquarters
- □ repacker
- □ pharmacy
- □ retailer
- □ hospital pharmacies
- □ hospital/medical facility
- □ Other:

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-893-5572.