URGENT: DRUG RECALL - REVISED

Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)

September 13, 2018

Dear Trading Partner,

This notice is to notify you of a product recall update involving:

Product Name	Brand Name	Lot Number	NDC Number	Expiration Date
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	N/A	RV1602RB	63304-241-59	07/2019
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	N/A	RV1604RB	63304-241-59	09/2019
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	N/A	RV1605RB	63304-241-59	10/2019

The depth of the recall was revised to the retail level.

See enclosed product label.

This recall has been initiated due a laboratory results that indicate a lower than expected potency. Use of this product would lead to a lower dose administered to patients.

Sun Pharma initiated shipment of this product on September 14, 2016.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your wholesale/retail customers and notify them at once of this product recall. Your notification to your wholesale/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.
4332 Empire Road
South Dock
Fort Worth, TX 76155

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-800-967-5952, 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.

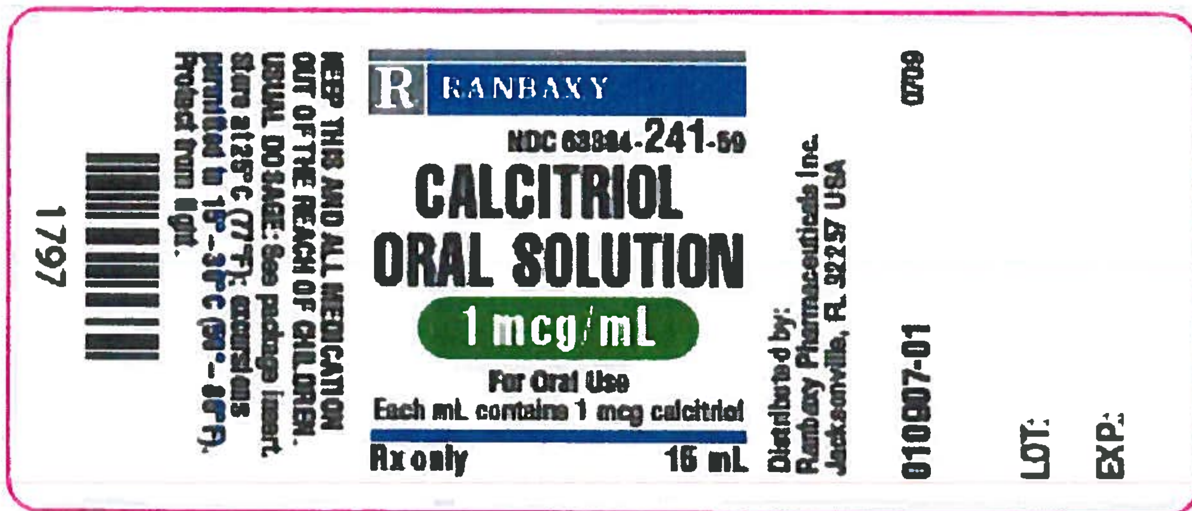
This recall is being made with the knowledge of the Food and Drug Administration.

Kristy Zielny
Director, Site Head of Quality- Cranbury
Sun Pharmaceutical Industries Ltd

Enclosure

Enclosure:

Calcitriol Oral Solution, 1 mcg/mL (15 mL vial) Bottle Labeling



URGENT: DRUG RECALL – RESPONSE FORM

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

Product Name	Lot Number	NDC Number	Expiration Date
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	RV1602RB	63304-241-59	07/2019
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	RV1604RB	63304-241-59	09/2019
Calcitriol Oral Solution, 1 mcg/mL (15 mL vial)	RV1605RB	63304-241-59	10/2019

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the September 13, 2018 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units (number of bottles).

□ 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 wholesale/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/retail 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 1-800-967-5952.

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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: ____________________________________

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