



EPIC PHARMA, LLC

227-15 North Conduit Avenue, Laurelton, NY 11413
Tel: 718-276-8600 Fax: 718-276-1735

URGENT: VOLUNTARY DRUG RECALL

***** NOTE: REVISED FROM A CLASS III TO CLASS II RECALL *****

February 7, 2019

Smith Drug Company
9098 Fairforest Road
Spartanburg, SC 29301

Dear Smith Drug Company:

This is to inform you of a product recall FDA RECLASSIFICATION involving:

Estradiol Tablets USP, 2 mg, 100-count bottles, NDC #42806-089-01, Lot #18103A, Expiration: June 2020

This Class II Recall letter requires notification to the **RETAIL level**. Your company should have already received a wholesale recall letter from Epic (sent on 12/04/18), which is now rendered obsolete by this recall re-categorization at the behest of the FDA.

Please review the enclosed product label.

This recall has been initiated due to a customer complaint stating a single foreign Meprobamate 400 mg tablet was found in a pharmacy-dispensed bottle of Estradiol Tablets USP, 2 mg, Lot #18103A. Based upon a conducted Health Hazard Assessment, consumption of the foreign tablet could potentially affect the safety or efficacy of the product.

Epic shipped this product to you on **07/19/18, 08/01/18, 08/02/18, and 8/03/18**

Please immediately examine your inventory and quarantine all quantities of Estradiol 2 mg Tablets, Lot #18103A.

Note this recall is isolated to 100-count bottles of Estradiol 2 mg Tablets, Lot #18103A only.

As per FDA evaluation, this is now reclassified as a Class II recall, thus this recall **MUST BE CONDUCTED TO THE RETAIL LEVEL**. Accordingly, please promptly extend this recall to all retailers that were distributed the specific lot mentioned above.

Please include a copy of this recall notification letter in your communications with your retailers.

Product returns may be sent to: **Epic Pharma, LLC, 227-15 North Conduit Avenue, Laurelton, NY 11413, Attn: QA**

Again, this recall should be carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent any potential patient harm.

Please complete and return the enclosed response form as soon as possible.

If you have any questions, feel free to contact Epic Customer Service at 1-888-374-2791. This voluntary recall is being conducted with the knowledge of the Food and Drug Administration.

Christopher Aupperlec, Quality Assurance
Epic Pharma LLC
227-15 North Conduit Avenue
Laurelton, NY 11413



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URGENT – PLEASE FILL OUT AND RETURN IMMEDIATELY

Regarding: **Estradiol Tablets USP, 2 mg, 100-Count Bottles, Lot Number 18103A**
Expiration Date: June 2020, NDC #42806-089-01

The aforementioned product, which was manufactured by Granulation Technology, Inc. and distributed by Epic Pharma, LLC, is the subject of a voluntary recall. The recall is isolated to one (1) lot of Estradiol Tablets USP, 2 mg, Lot #18103A. The recall is extended to the RETAIL level.

Per our records, Epic has shipped the following purchase orders using Lot Number 18103A.

Lot Number	Units Shipped	Ship Dates
18103A	216	07/19/18 - 08/03/18

Please immediately examine your inventory. This lot should be **QUARANTINED** and **RETURNED** to Epic Pharma immediately, at the following address:

Epic Pharma, LLC, 227-15 North Conduit Avenue, Laurelton, NY 11413, Attention: QA

Our Federal Express account number is 435418589. Our UPS account number is 8F3Y63. If you wish to use carriers other than these, please bill us for the shipment.

Please check ALL appropriate boxes and verify by signing below.

- I have read and understand the recall instructions provided in the letter.
- I have checked my stock and have quarantined inventory consisting of _____ bottles.
OR
- We do not have any stock of Estradiol 2 mg Tablets, Lot #18103A, bottles of 100's.

If you have inventory of this product, please include this completed form with the returned bottles. If you do not have any inventory, please forward the completed form to the above address, or fax to 718-949-3120, or send via email to returns@epic-pharma.com. If you have any questions, please contact Epic at its customer service number: 1-888-374-2791.

NOTE: Please designate prefix "RCRA-445" on any shipments being returned per this recall.

Signature: _____ Printed Name: _____

Title: _____ Date: _____

Phone Number: _____ Company Name: _____

Company Location: _____



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Smith Drug Company:

***Please see attached list of distribution centers that were shipped the affected lot.**

Note this recall must be conducted to the RETAIL level.

Item	Description	Ship Date	City	St	Lot/Serial	Qty Shipped
42806-089-01	Estradiol 2 mg USP	07/19/18	Spartanburg	SC	18103A	48
42806-089-01	Estradiol 2 mg USP	07/19/18	Valdosta	GA	18103A	24
42806-089-01	Estradiol 2 mg USP	08/01/18	Spartanburg	SC	18103A	48
42806-089-01	Estradiol 2 mg USP	08/02/18	Paragould	AR	18103A	72
42806-089-01	Estradiol 2 mg USP	08/03/18	Spartanburg	SC	18103A	24

~~05/18~~
2/9/17

LOT: 18103A
EXP: 06/2020



USUAL DOSAGE: See accompanying literature for complete prescribing information.

Store at 20° to 26°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense contents in a tight, light-resistant container as defined in the USP, with a child-resistant closure, as required.

Rev. 02-2017-00 LE3366

NDC 42806-089-01

Estradiol Tablets, USP

2 mg

PHARMACIST: Dispense the accompanying Patient Information Leaflet to each patient.

Rx Only
100 Tablets



Each tablet contains:
Estradiol, USP ... 2 mg

KEEP TIGHTLY CLOSED

KEEP THIS AND ALL
MEDICATION OUT OF THE
REACH OF CHILDREN.

Distributed by:
Epic Pharma, LLC
Cannellton, PA 15313

RG
7-9-18

00000 Epic Pharma LLC
Laurelton, NY 11413
Estradiol Tablets, USP 2 mg 24 PO BX

42806-089-01

Qty: 00024 EXP: 0620 LOT: 18103A

(22) 9 00024 0620 18103A 9



N (01) 3 03 42806-089-01 9 (30) 00024

Epic Pharma LLC
Laurelton, NY 11413

Estradiol Tablets, USP 2 mg 24 PO BX

42806-089-01

Qty: 00024 EXP: 0620 LOT: 18103A

(22) 9 00024 0620 18103A 9



N (01) 3 03 42806-089-01 9 (30) 00024