



August 13, 2021

URGENT DRUG RECALL FOR

SODIUM PHENYLBUTYRATE POWDER, 250 GRAMS

Dear Valued Customer:

This is to inform you of a voluntary product recall involving Sigmapharm's Sodium Phenylbutyrate Powder, 250 Grams for the lot numbers listed below.

Product	NDC Number	UPC Code	Lot Numbers	Expiration Dates	Distribution Dates	Manufacturer and Distributor
Sodium Phenylbutyrate Powder, 250 Grams	42794-086-14	3 4279408614 4	1813001	May-2023	9/11/2018 – 11/14/2018	Sigmapharm Laboratories, LLC
			1813101	May-2023	11/14/2018 – 1/22/2019	
			1813201	May-2023	1/7/2019 – 4/23/2019	
			1822601	Nov-2023	4/11/2019 – 11/12/2020	
			1822701	Nov-2023	7/1/2019 – 9/4/2019	
			1905701	May-2024	8/27/2019 – 11/18/2019	
			1905801	May-2024	11/18/2019 – 1/22/2020	
			1906501	May-2024	1/17/2020 – 3/23/2020	
			1906601	May-2024	2/24/2020 - 6/8/2020	
1906701	May-2024	6/15/2020 – 11/2/2020				

See enclosed product label for further ease in identifying the product.

This recall has been initiated due to the out of-specifications (OOS) impurity results obtained during routine quality testing of a stability sample for one lot of Sodium Phenylbutyrate Powder, 250 Grams. This recall is being extended to all other potentially impacted lots as mentioned in the table above. Use of this product is not likely to cause any adverse health consequences.

We began shipping this product on September 11, 2018.

We ask for your cooperation in taking the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately stop distribution of these lots.
3. A credit memo will be issued covering the quantity of your product returned.

Return product to: Eversana
 c/o SigmaPharm recall
 ATTN: Returns Department
 4580 S. Mendenhall
 Memphis, TN 38141



NOTE: To request a prepaid shipping label please complete and return the enclosed "Customer Recall Return Response Form" to the email or fax below (section 5). The prepaid shipping label will be sent to the email address provided. The email will be coming from EVERSANA within 5 business days. Please check the spam folder if you do not see it in your inbox. **Please note the FedEx link is only valid for 10 days.**

*Wholesalers please send debit memo via email or fax (section 5).

4. If you have further distributed this product to other wholesalers or retailers, please identify and notify them at once of this product recall. **Your notification should include a copy of this recall notification letter and customer recall return response form.**
5. Even if you do not have the recalled product in your inventory, please complete and return the enclosed "Customer Recall Return Response Form," even if you do not have any inventory, as soon as possible and email the form to us at DDNRegulatory@Eversana.com and CC: SigmaPharmCS@Eversana.com. The completed form may also be faxed to 1- 414-434-6690.

This recall should be carried out to the **Retail Level**. Your assistance is appreciated and necessary to prevent further distribution of the product.

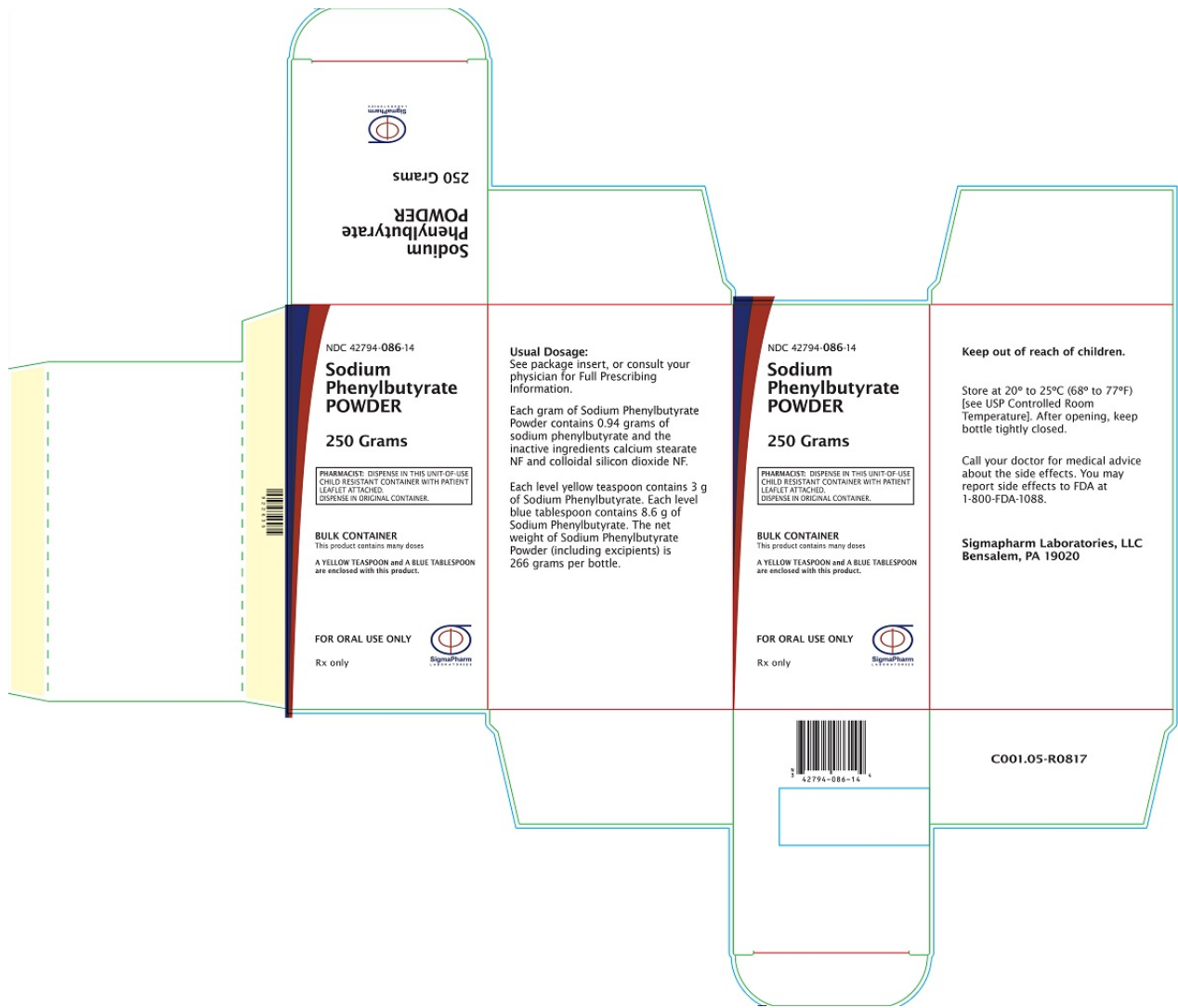
If you have any questions related to the return of these products, contact Customer Service at 1-855-206-7815, option 1 on Monday through Friday between 8 am – 7 pm CST. If you have any other questions related to this recall, please contact Sigmapharm's Sales & Marketing Department: Mr. McKee Moore (at 215-352-6655, Ext 258) or Mr. Robert Citrino (at 215-352-6655, Ext 259).

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

Sincerely,

A handwritten signature in black ink that reads "Prakash Patel". The signature is written in a cursive, flowing style.

Prakash Patel
Senior Vice President, Quality Operations Division
SigmaPharm Laboratories, LLC
Enclosure(s):
Product Labels
Customer Recall Return Response Form



NDC 42794-086-14

Sodium Phenylbutyrate POWDER


250 Grams

PHARMACIST: DISPENSE IN THIS UNIT-OF-USE CHILD RESISTANT CONTAINER WITH PATIENT LEAFLET ATTACHED. DISPENSE IN ORIGINAL CONTAINER.

BULK CONTAINER
This product contains many doses.

A YELLOW TEASPOON and A BLUE TABLESPOON are enclosed with this product.

FOR ORAL USE ONLY
Rx only



Store at 20° to 25°C (68° to 77°F)
[see USP Controlled Room Temperature]. After opening, keep bottle tightly closed.


Each gram of Sodium Phenylbutyrate Powder contains 0.94 grams of sodium phenylbutyrate and inactive ingredients calcium stearate NF and colloidal silicon dioxide NF.

Each level yellow teaspoon contains 3 g of Sodium Phenylbutyrate.
Each level blue tablespoon contains 8.6 g of Sodium Phenylbutyrate.
The net weight of Sodium Phenylbutyrate Powder (including excipients) is 266 grams per bottle.

Usual Dosage: See package insert, or consult your physician for Full Prescribing Information.

Call your doctor for medical advice about the side effects. You may report side effects to FDA at 1-800-FDA-1088.

Sigmapharm Laboratories, LLC
Bensalem, PA 19020



N 42794-086-14 4

L038.05-R0817



August 13, 2021

RECALL RETURN RESPONSE FORM

RECALL OF SODIUM PHENYLBUTYRATE POWDER, 250 GRAMS

Product	NDC Number	UPC Code	Lot Numbers	Expiration Date	Distribution Date	Qty. To Be Returned
Sodium Phenylbutyrate Powder, 250 Grams	42794-086-14	3 4279408614 4	1813001	May-2023	9/11/2018 – 11/14/2018	
			1813101	May-2023	11/14/2018 – 1/22/2019	
			1813201	May-2023	1/7/2019 – 4/23/2019	
			1822601	Nov-2023	4/11/2019 – 11/12/2020	
			1822701	Nov-2023	7/1/2019 – 9/4/2019	
			1905701	May-2024	8/27/2019 – 11/18/2019	
			1905801	May-2024	11/18/2019 – 1/22/2020	
			1906501	May-2024	1/17/2020 – 3/23/2020	
			1906601	May-2024	2/24/2020 - 6/8/2020	
			1906701	May-2024	6/15/2020 – 11/2/2020	

Please check ALL appropriate boxes.

I have read and understand the recall instructions provided in the August 13, 2021 letter.

I have checked my stock and do not have any of the recalled product.

I have checked my stock and have quarantined inventory consisting of _____ <units or cases>.

Indicate disposition of recalled product:

returned (specify quantity: _____, date: _____ and method : _____) /held for return;

destroyed (specify quantity: _____, date: _____ and method : _____);

I would like to receive a pre-paid return label.

Total number of Call Tags (Number of Boxes you will be returning): _____

Return product to:

Eversana Life Science Services
 c/o SigmaPharm Recall
 ATTN: Returns Department
 4580 S. Mendenhall Rd.
 Memphis, TN 38141



Note: A prepaid shipping label will be sent to the email address provided below. The email will be coming from EVERSANA within 5 business days. Please check the spam folder if you do not see it in your inbox. Please note the FedEx link is only valid for 10 days.

I have or will contact those further distributed to. This recall is to the Retail Level.

Any adverse events associated with recalled product? Yes NO

If yes, please explain: _____

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

- wholesaler/distributor retailer grocery corporate headquarters food service/restaurant
- repacker manufacturer pharmacy retail
- hospital/medical facility hospital pharmacies medical laboratory
- Other: _____

*Wholesaler required field

Contact Information:

Name: _____ Date: _____

Title: _____ Tel Number: _____

Email: _____

Facility Name: _____

Facility Address: _____ City: _____ State: _____ Zip: _____

*Debit Memo _____

**Pharmacy required fields

**Wholesaler: _____ **WholesalerAccount#: _____

** Pharmacy DEA # _____

Even if you do not have any inventory, please send this completed recall response form to: Email

DDNRegulatory@Eversana.com and SigmaPharmCS@Eversana.com or Fax 1-414-434-6690.

If you have any questions related to the return of these products, contact Customer Service at 1-855-206-7815, option 1 on Monday through Friday between 8 am – 7 pm CST. If you have any other questions related to this recall, please contact Sigmapharm's Sales & Marketing Department: Mr. McKee Moore (at 215-352-6655, Ext 258) or Mr. Robert Citrino (at 215-352-6655, Ext 259).

Sincerely,

Prakash Patel
Senior Vice President, Quality Operations Division
Sigmapharm Laboratories, LLC

Sigmapharm Laboratories, LLC • 3375 Progress Drive • Bensalem, PA 19020 • USA
Tel: +01 215-352-6655 • Fax: +01 215-352-6644 • www.sigmapharm.com

