



MANUFACTURING / R&D
85 ADAMS AVENUE
HAUPPAUGE, NY 11788

866.525.7270 main
866.525.7271 fax

amneal.com

August 16, 2013

URGENT DRUG RECALL – Lot does not meet dissolution specification

Re: Phenytoin Sodium Capsules, USP 100 mg, Lot HL50611, NDC 65162-212-11

Amneal Pharmaceuticals has confirmed that Lot HL50611 did not meet dissolution specification during analysis of an 18-month stability test sample. Consequently we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you Lot HL50611 on hand. If so, please discontinue distributing this lot and promptly return to our Glasgow, KY warehouse, located at 118 Beaver Trail, Glasgow, KY 42141, marked ATTENTION: RETURN GOODS – PRODUCT RECALL. Call our returns department at 866-565-7365 to get an RGA number.

If you have distributed this lot, please forward this recall announcement to your customers at the wholesale and retail level. Return these stocks as indicated above.

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed response form immediately (by FAX, email, or in the prepaid envelope) providing the requested information.

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

We appreciate your assistance in this matter.

A handwritten signature in black ink that reads "Raj Sutaria".

Raj Sutaria
Vice President, Quality Assurance - USA



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RECALL RESPONSE FORM

**PLEASE FILL OUT AND RETURN PROMPTLY BY MAIL, EMAIL (cwatson@amneal.com),
OR FAX IT TO: 866-525-7626**

- We do not have any stock of Phenytoin Sodium Capsules, USP 100 mg, Lot HL50611.
- We are returning _____ units of Phenytoin Sodium Capsules, USP 100 mg, Lot HL50611.
- We have not received any complaints of illness/injury regarding Phenytoin Sodium Capsules, USP 100 mg, Lot HL50611.
- We have requested our accounts to return their stock of this lot to us.

Account Name:		
Address:		
City:	State:	Zip:
Signature:	Date:	