



MEDICAL SUPPLY BULLETIN

HHS SUPPLY SERVICE CENTER

PERRY POINT, MD 21902

We Service the World

Steven Pearson, Director

Annette Quiñones, R.Ph., Editor

BULLETIN NO. 4

July 21, 2009

URGENT PRODUCT RECALL

Dear Valued Customers:

Taro Pharmaceuticals is voluntarily recalling Fluocinonide Cream, USP 0.05%, 15 gm and 120 gm tubes due to out-of-specification tube uniformity values. These values observed at 18 and 34 months stability intervals revealed the deviation. However, Taro believes that this product does not create a health hazard.

The 15 gm tube was distributed by Taro from 10/10/06-04/17/09, and the 20 gm tube from 12/29/06-03/12/09. The affected lots are indicated here and this recall only affects two packaging sizes (15 gm and 120 gm).

An assessment of our inventory shows that the Center stocks the 15gm under 6505-00-149-0160.

Fluocinonide Cream USP 0.05%		
N.D.C	Size	Affected Lot(S)
5167-1253-01	15GM	6E134 G6091 I6030 K6042 L6034 D7085 G7044 I7107 L7057 B8039 B8041 D8115 F8028 F8029 H8028 I8049 K8114 L8070
51672-1253-04	120GM	6E134 J6079 H7088 B8041 H8028 J8025

We ask for your cooperation in taking the following action:

- Please examine your inventory immediately and if you have the recalled product in question immediately cease distribution/ use.
- Return all recall products directly to:

ATTN: Returned Goods-Recall-Fluocinonide Cr. 0.05%
Taro Pharmaceuticals U.S.A. Inc,
1 Commerce Drive,
Cranbury, NJ 08512

- For questions regarding this recall, please contact Taro Pharmaceutical at 1-800-544-1449. This recall is being conducted with the knowledge of the Food and Drug Administration.

We apologize for any inconvenience this recall presents, and thank you in advance for your prompt attention to this urgent request.


Steven Pearson
Director