NATIONAL PBM COMMUNICATION · April 4, 2014

Alli® (Orlistat) Recall of All Lots Due to Tampering

- The manufacturer of the weight loss product Alli® (Orlistat) issued a voluntary recall of all lots from the U.S. market due to package tampering, including:
  - bottles without labels,
  - broken safety seals, and
  - bottles containing pills other than Alli®.

PRODUCT SEQUESTERING ACTIONS

- Following the action due dates in **Product Recall Office Log # 8050** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.
- ALL LOTS are being recalled. Lots reported to date with signs of tampering are included on pages 2 and 3.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) for home administration by any appropriate method.
    - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc
  - Provide patient(s) in possession of the recalled product with instructions on the following:
    - How to return the product being recalled to the pharmacy.
    - How to obtain a new supply of product.
    - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
    - Alli® is a turquoise blue capsule with a dark blue band imprinted with the text "60 Orlistat." It is packaged in a labeled bottle that has an inner foil seal imprinted with the words: "Sealed for Your Protection." Pictures of the product are available on the following website: www.myalli.com .

- Providers should continue to report any adverse reactions with the use of orlistat (Alli®) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

REFERENCES:

1. FDA warns consumers not to purchase or use weight loss product Alli®. http://www.fda.gov/Drugs/DrugSafety/ucm391046.htm . (Accessed 04/02/2014).
2. GLAXOSMITHKLINE recall Alli®. http://www.myalli.com/weight-loss-news-press-room/march-27-2014/ . (Accessed 04/02/2014).
3. GSK reports alli® product tampering, alerts consumers to unknown product in alli® packages. http://us.gsk.com/html/media-news/pressreleases/2014/gsk-reports-alli--product-tampering--alerts-consumers-to-unknown.html . (Accessed 04/02/2014).

FEEDBACK NOTIFICATION ACTIONS:

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, MOVE! Program providers, and pharmacy staff, including contract providers****, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*
- ***VISN Directors:*** *Within 10 business days of issue (due 04/18/2014), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx .*

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Alli® (Orlistat) Recall of All Lots Due to Tampering *(continued from page 1)*

Lots that have already been reported with signs of tampering:

Material Description	Item Number	Manufacturer NDC/UPC	LOT # - Expiration Date	Manufacturer Initial Ship Date
ALLI STARTER 60 MG CAP 90	10041532 630297	0135046102	12K28N - 04/30/2015 12L04W - 04/30/2015 12L06N - 04/30/2015 12L11W - 04/30/2015 13358 - 09/30/2014 13425 - 11/30/2104 13545 - 12/31/2014 13565 - 12/31/2014 13595 - 01/31/2015 13635 - 01/31/2015 13707 - 03/31/2015 13730 - 03/31/2015 13765 - 04/30/2015 13788 - 04/30/2015 13824 - 05/31/2015 13901 - 05/31/2015 13K13W - 02/28/2016 13K14N - 02/28/2016 13K20N - 02/28/2016 14042 - 08/31/2015 14075 - 08/31/2015 14095 - 09/30/2015 14267 - 01/31/2016 14287 - 01/31/2016 14395 - 02/28/2016	09/01/2011
ALLI CAPLET 60MG REFILL 120CT	10041533 630309	053100469253	12994 - 04/30/2014 13376 - 10/30/2014 13411 - 11/30/2014 13448 - 11/30/2014 13483 - 12/31/2014 13568 - 12/31/2014 13596 - 01/31/2015 13670 - 03/31/2015 13706 - 03/31/2015 13720 - 03/31/2015 13746 - 04/30/2015 13752 - 10/31/2015 13789 - 04/30/2015 13809 - 04/30/2015 13852 - 05/31/2015 13903 - 06/30/2015 13L26N - 04/30/2016 14009 - 08/31/2015 14077 - 08/31/2015 14124 - 09/30/2015 14245 - 11/30/2015 14283 - 01/31/2016 14319 - 02/28/2016 14372 - 02/28/2016 14409 - 03/31/2016 14442 - 04/30/2016 14535 - 04/30/2016	09/01/2011

Alli® (Orlistat) Recall of All Lots Due to Tampering *(continued from page 2)*

Material Description	Item Number	Manufacturer NDC/UPC	LOT # - Expiration Date	Manufacturer Initial Ship Date
ALLI STARTER PACK CAPSULE 90CT	10098857 130187	0135046102	12K28N - 04/30/2015 12L04W - 04/30/2015 12L06N - 04/30/2015 12L11W - 04/30/2015 13358 - 09/30/2014 13425 - 11/30/2104 13545 - 12/31/2014 13565 - 12/31/2014 13595 - 01/31/2015 13635 - 01/31/2015 13707 - 03/31/2015 13730 - 03/31/2015 13765 - 04/30/2015 13788 - 04/30/2015 13824 - 05/31/2015 13901 - 05/31/2015 13K13W - 02/28/2016 13K14N - 02/28/2016 13K20N - 02/28/2016 14042 - 08/31/2015 14075 - 08/31/2015 14095 - 09/30/2015 14267 - 01/31/2016 14287 - 01/31/2016 14395 - 02/28/2016	09/01/2011

Additional affected lots identified from the manufacturer, GlaxoSmithKline :

Voluntary Recall of alli® 60mg Capsules Item Number	Product Description	Retail UPC	Case Code UPC	NDC Number
46860	Alli Starter Kit 90ct 6x90 ct	353100468004	10353100468605	0135-0461-02
46869	Alli 90ct w/cookbook – Target 6x90ct	353100468691	10353100468698	0135-0461-02
46870	Alli 90ct PDQ w/cookbook promo 6x90ct	353100468691	00353100468707	0135-0461-02
46925E	Alli Refill Pack 120ct 6x120ct	353100469254	10353100469251	0135-0461-05
46925G	Alli Refill Pack 120ct 6x120ct	353100469254	10353100469251	0135-0461-05
46928	Alli 8pc 120ct Side Kick WalMart 8x120ct	353100469254	00353100469285	0135-0461-05
46930	Alli 8pc 90ct Side Kick WalMart 8x90ct	353100468004	00353100469308	0135-0461-02
46977	Mixed Brand Tower 6 SKU 21pcs CVS	353100468004	00353100469773	0135-0461-02
47202	Alli 170ct Refill 6x170ct	353100472001	10353100472022	0135-0461-06
47218	Alli 170ct 36 pc Pallet Sam's 36x170ct	353100472216	00353100472186	0135-0461-06
47219	Alli 170ct 162 pc Pallet Costco 162x170ct	353100472216	00353100472193	0135-0461-06
47221	Alli 170ct Club Tray 9x170ct	353100472216	10353100472213	0135-0461-06