

Enforcement Report - Week of March 30, 2016

Biologics	Cosmetics	Devices	Drugs	Food	Tobacco
Veterinary					

Class II Drugs Event

Event ID:

72796

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

AGA Gas Inc
6055 Rockside Woods Blvd
Independence OH United States

Recall Initiation Date:

11/29/2015

Center Classification Date:

03/18/2016

Date Terminated:

Associated Products

Product Description:

Oxygen, USP, 99.0%, Bulk Cryogenic
Liquid, Rx, Airgas Merchant Gases,
LLC, Independence, OH --- NDC
33237-001-01

Product Quantity:

1,500 gallons

Code Information:

Lot# 7931-O-V32-5330-5-1062

Voluntary / Mandated:

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Distribution Pattern:

Product was delivered to Ohio

Reason for Recall:

cGMP Deviations; trailer may not have
met GMP requirements prior to filling

Recall Number:

D-0779-2016

Class II Drugs Event

Event ID:
Voluntary / Mandated:

73434

Voluntary: Firm Initiated

Product Type:

Drugs

Initial Firm Notification of Consignee or Public:

Letter

Status:

Ongoing

Distribution Pattern:

Nationwide and Puerto Rico

Recalling Firm:

Sagent Pharmaceuticals Inc
1901 N Roselle Rd Ste 700
Schaumburg IL United States

Recall Initiation Date:

03/01/2016

Center Classification Date:

03/22/2016

Date Terminated:**Associated Products****Product Description:**

Fluconazole Injection, USP (in 0.9% Sodium Chloride), 200 mg per 100 ml, Single-Dose Container Bag, Rx only, Mfd. for SAGENT Pharmaceuticals, Schaumburg, IL 60195, NDC 25021-0113-82

Reason for Recall:

Cross contamination with other products: metronidazole

Product Quantity:

37,450 bags

Recall Number:

D-0780-2016

Code Information:

Lot #: 40608, Exp 5/17

Class II Drugs Event**Event ID:**

73538

Voluntary / Mandated:

Voluntary: Firm Initiated

Product Type:

Drugs

Initial Firm Notification of Consignee or Public:**Status:**

Ongoing

Distribution Pattern:

US: Nationwide Including Puerto Rico

Recalling Firm:

AstraZeneca Pharmaceuticals LP
1800 Concord Pike, P.O. Box 15437
Health Services Medical FOC 1

Wilmington DE United States

Recall Initiation Date:

02/05/2016

Center Classification Date:

03/22/2016

Date Terminated:**Associated Products****Product Description:**

Tudorza Pressair (aclidinium bromide inhalation powder), 400 mcg per actuation, 60 Metered Doses per Inhaler, Rx Only. Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. Manufactured by: Forest Laboratories, Ireland Limited, Dublin 17 Ireland. Product of Spain. NDC: 0310-0800-60.

Product Quantity:

148,331 Inhalers

Code Information:

Lot # 1144394, Expiry: 04/2018; Lot # 1145539, Expiry: 04/2018; Lot # 1145868, Expiry: 05/2018.

Reason for Recall:

Defective Delivery System: Some units have actuation counters set to a number other than 60.

Recall Number:

D-0781-2016