

Enforcement Report - Week of July 4, 2018

Class II Drugs Event

Event ID:

80354

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/20/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

06/25/2018

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:

Distributed to one medical center in Fort Worth, TX.

Associated Products

Product Description:

fentanyl Citrate USP 5 mcg in 0.9% Sodium Chloride USP 0.5 mL, 10 mcg per mL prefilled syringe, Rx only, Advanced Pharma an FDA Regulated 503B Outsourcing Facility 9265 Kirby Dr., Houston, TX 77054, NDC 15082-210-72.

Product Quantity:

100 syringes

Reason for Recall:

Subpotent Drug: final drug concentration is subpotent as compared to the concentration indicated on the label.

Recall Number:

D-0889-2018

Code Information:

Lot #: 6/12/18 0432 149-21072S, BUD 9/10/18