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COM 2019-013

Recall: Apotex Corp. Issues Voluntary Nationwide Recall of Drospirenone and Ethinyl Estradiol Tablets, USP

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on March 4, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Apotex Corp. is voluntary recalling four lots of Drospirenone and Ethinyl Estradiol Tablets, USP. The recall was made because these lots may possibly contain defective blisters with incorrect tablet arrangements and/or an empty blister pocket. The products affected by the recall are detailed on Table 1.

Table 1. Affected product of Drospirenone and Ethinyl Estradiol

NDC number on outer carton	NDC Number on inner carton	Lot number	Expiration Date	Strength	Configuration/Count
60505-4183-3	60505-4183-1	7DY008A 7DY009A 7DY010A 7DY011A	8/2020	3MG / 0.03MG	- Outer Carton: Contains three inner Cartons - Inner Carton: Contains 1 blister with 21 active yellow color tablets and 7 placebo white color tablets

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should not discontinue taking the medication without a doctor's permission.
3. Contact Apotex corp. at 1-800-706-5575 for any questions regarding recalled product. Normal business hours are Monday through Friday 8:30 a.m. to 5:00 p.m. EST.

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm632629.htm

Department of Clinical Pharmacy

6 Street 1, Suite 101, Guaynabo, PR 00968-1770 Tel. 787.522.5252 | Fax 1.866.912.2830 www.pharmpix.com