September 23, 2020 **COM-2020-068**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

September 21, 2020

DRUG NAME: Albuterol sulfate inhaler

COMPANY: Catalent Pharma Solutions, Perrigo Pharmaceutical Company

REASON: Possible clogging of inhaler resulting in lesser amount of drug delivered to patient.

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we are notifying you that on September 21, 2020, the US Food and Drug Administration (FDA) published a voluntary recall for all unexpired albuterol sulfate inhalation aerosol manufactured by Catalent Pharma Solutions for Perrigo Pharmaceutical Company.

The voluntary recall is due to possible clogging of the device, resulting in fewer drugs delivered to patients. The patients may face a health risk since the product may not provide relief to airway obstruction symptoms. However, the FDA urges patients to continue using their current inhaler. The FDA also advises patients to seek emergency care if needed and use an extra inhaler if the recalled inhaler stops working after several uses.

Pharmacy required actions(s):

- Identify if the product is inventory and immediately stop using and dispensing it. The recall is to the retail level.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription. Advises patients to keep and use an extra inhaler if the recalled inhaler stops working after several uses. If symptoms of airway obstruction are not relieved, seek emergency care.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

URAC ACCREDITED Pharmacy Benefit Management Expires 12/01/2022

- For further information: Perrigo Recall Contact, Stericycle 877-907-9964, for the questions about the recalled product.

Contact information:

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at:

- FDA Recall for Albuterol Sulfate Inhaler
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2020). FDA Alerts of Perrigo's voluntary albuterol inhaler recall. Retrieved September 23, 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-perrigos-voluntary-albuterol-inhaler-recall

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2022

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com