URGENT DRUG RECALL
AirDuo® Digihaler®
INITIATED 09/22/2021

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling three lots of AirDuo® Digihaler® (fluticasone propionate and salmeterol) Inhalation Powder, to the RETAIL LEVEL. These lots were distributed under the labels for Teva Pharmaceuticals USA, Inc.

NDC	Lot	Exp. Date	Product Name	Size	Shipping Dates
59310-111-06	AFR16A	01/2022	AirDuo® Digihaler® 55/14 (fluticasone propionate 55 mcg and salmeterol 14 mcg) Inhalation Powder	60 METERED INHALATIONS	09/15/2020 - 03/03/2020
59310-129-06	AFR17A	01/2022	AirDuo® Digihaler® 113/14 (fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder	60METERED INHALATIONS	09/15/2020 - 03/05/2021
59310-136-06	AFR18A	11/2021	AirDuo® Digihaler® 232/14 (fluticasone propionate 232 mcg and salmeterol 14 mcg) Inhalation Powder	60 METERED INHALATIONS	09/15/2020 - 03/11/2021

This recall is being initiated because during routine stability testing of these lots, results for Salmeterol were below the approved specification limits. It is important to note that Fluticasone Propionate stability testing results are within approved specification limits. At the time of commercial release to the market, these three lots met all release requirements.

The possible consequence of receiving Salmeterol doses below specification limits would be a decrease in treatment efficacy, potentially resulting in reduced asthma control and/or overuse of quick-relief medications, such as with a short-acting beta-agonists (SABAs), with their associated risks. To date, Teva has not received any product quality complaints or adverse event reports related to low Salmeterol dose. Exposure to the product of concern could lead to mild adverse events but the likelihood of occurrence is remote. Therefore, the overall risk of harm in the patient population is considered to be low.

This recall is being made with the knowledge of the Food and Drug Administration.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the products and lots given in table above.
- Immediately discontinue distribution of the specified product lots affected by this recall.
- Refer to table for shipping dates of these recalled products.
- **If you have further distributed these lots, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form (SRF) as a basis for your SUB-RECALL letter.**
- Even if you have **no** product to return, promptly complete the attached recall SRF and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator:

  Inmar, 635 Vine Street, Winston Salem, NC 27101
  Email address: **rxrecalls@inmar.com**
  FAX: 817-868-5362

Inmar will send labels for Return Goods Authorization (RGA) and shipping after receipt of your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns and Stock Response Forms: Contact Inmar at the dedicated phone line: 855-801-5048. Hours of Operation: M – F, 9.00 AM to 5.00 PM Eastern Time Recall Stock Response Forms - Contact Inmar at 855-801-5048 or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-483-8279 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name:	
*DEA #:	*Debit Memo #

**The DEA # and the Debit Memo # are required; in order to process your form.*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Additional Stock Response Forms included: ***Yes*** ☐ ***No*** ☐

NDC	Lot #	Quantity to Return (# of Inhalers)
59310-111-06	AFR16A	
59310-129-06	AFR17A	
59310-136-06	AFR18A	

I have checked my stock and:

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Please return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to:
Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B