

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Teva Pharmaceuticals USA, Inc. (TEVA USA) is conducting a nationwide Market Withdrawal of all its Digihaler® products that are within expiry to the **RETAIL LEVEL**. The Digihaler® products in this Market Withdrawal were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label. The reason for the Market Withdrawal is because the Digihaler® App and Dashboard is no longer available, which does not align with the patient information leaflet for each of these Digihaler® products. Teva USA’s safety assessment concluded that unavailability of the Digihaler® App and Dashboard is not clinically relevant given that the digihaler devices will still function with no impact to delivery of the medicine. As such, exposure to the subject Digihaler® products of concern is not expected to lead to adverse health consequences outside the known safety profile of the respective drug.

TEVA’s distribution records indicate that the specified Digihaler® lots being Withdrawn were shipped to its direct customers from 03/02/2022 - 05/16/2024.

Digihaler® Products for Market Withdrawal

Product Description	NDC	Lot #	Exp. Date	Pack size
AirDuo® Digihaler® 55/14  (fluticasone propionate 55 mcg and salmeterol 14 mcg)  Inhalation Powder	59310-111-06	AGA97A	Aug-2024	1 Inhaler / Carton
AirDuo® Digihaler® 113/14	59310-129-06	14345	Jul-2025	1 Inhaler / Carton

(fluticasone propionate 113 mcg and salmeterol 14 mcg)

Inhalation Powder

AirDuo® Digihaler® 113/14

(fluticasone propionate 113 mcg and salmeterol 14 mcg)

59310-129-06 AGA40A Jun-2024

1 Inhaler /  
Carton

Inhalation Powder

AirDuo® Digihaler® 232/14

(fluticasone propionate 232 mcg and salmeterol 14 mcg)

59310-136-06 14346 Jul-2025

1 Inhaler /  
Carton

Inhalation Powder

AirDuo® Digihaler® 232/14

(fluticasone propionate 232 mcg and salmeterol 14 mcg)

59310-136-06 AGA70A Aug-2024

1 Inhaler /  
Carton

Inhalation Powder

ArmonAir® Digihaler® 55

(fluticasone propionate 55 mcg) Inhalation Powder

59310-114-06 AFX42A Sep-2024

1 Inhaler /  
Carton

ArmonAir® Digihaler® 113 (fluticasone propionate 113 mcg) Inhalation Powder	59310-200-06	AGC77A	Jan-2026	1 Inhaler / Carton
ArmonAir® Digihaler® 113 (fluticasone propionate 113 mcg) Inhalation Powder	59310-200-06	AGB24A	Sep-2025	1 Inhaler / Carton
ArmonAir® Digihaler® 232 (fluticasone propionate 232 mcg) Inhalation Powder	59310-311-06	AGB25A	Sep-2025	1 Inhaler / Carton
ProAir digihaler (albuterol sulfate) Inhalation Powder	59310-117-20	AGC69A	Feb-2026	1 Inhaler / Carton
ProAir digihaler (albuterol sulfate) Inhalation Powder	59310-117-20	AGB97A	Nov-2025	1 Inhaler / Carton
ProAir digihaler (albuterol sulfate) Inhalation Powder	59310-117-20	AGB60A	Oct-2025	1 Inhaler / Carton
ProAir digihaler (albuterol sulfate) Inhalation Powder	59310-117-20	AFZ45A	Mar-2025	1 Inhaler / Carton
ProAir digihaler (albuterol sulfate) Inhalation Powder	59310-117-20	AFZ45B	Mar-2025	1 Inhaler /

ProAir digihaler (albuterol sulfate) Inhalation Powder 59310-117-20 AGC70A Feb-2026

Carton

1 Inhaler /

Carton