## GEORGIA STATE BOARD OF PHARMACY

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## **SAFETY ALERT**

## NOTIFICATION OF COMPROMISED DRUG PRODUCTS SAFETY ALERT ISSUED BY THE GEORGIA STATE BOARD OF PHARMACY

Dear Licensee,

This letter is to inform you of a safety alert involving the products listed below, which were distributed by AlphaMed Rx, Inc., Georgia License No.: PHWH004962, 367 Athens Highway, Suite 1500, Loganville, Georgia 30052, from May 1, 2023 through May 21, 2025.

Admelog Solostar (insulin lispro)	Advair (fluticasone propionate and salmeterol)
Aimovig (erenumab-aooe)	Anoro Ellipta (umeclidinium and vilanterol)
Apidra Solostar (insulin glulisine)	Arnuity Ellipta (fluticasone furoate)
Atrovent (ipratropium bromide)	Basaglar (insulin glargine)
Bevespi Aerosphere (glycopyrrolate and	Biktarvy (bictegravir, emtricitabine, and
formoterol fumarate)	tenofovir alafenamide)
Breo Ellipta (fluticasone furoate and vilanterol)	Brilinta (ticagrelor)
Bydureon (exenatide)	Bystolic (nebivolol)
Combivent (ipratropium bromide and	Descovy (emtricitabine and tenofovir
albuterol)	alafenamide)
Dovato (dolutegravir and lamivudine)	Duexis (Ibuprofen and famotidine)
Dulera (mometasone furoate and formoterol	Dupixent (dupilumab)
fumarate dihydrate)	
Eliquis (apixaban)	Enbrel (etanercept)
Farxiga (dapagliflozin)	Fiasp (insulin aspart)
Flovent (fluticasone propionate)	Genvoya (elvitegravir, cobicistat,
	emtricitabine, and tenofovir alafenamide)
Humalog (insulin lispro)	Humira (adalimumab)
Incruse Ellipta (umeclidinium)	Invega (paliperidone palmitate)
Invokana (canagliflozin)	Isentress (raltegravir)
Janumet (sitagliptin and metformin	Januvia (sitagliptin)
hydrochloride)	
Jardiance (empagliflozin)	Juluca (dolutegravir and rilpivirine)
Lantus (insulin glargine)	Levemir (insulin detemir)
Levonorgestrel	Linzess (linaclotide)
Mounjaro (tirzepatide)	Myrbetriq (mirabegron)
Novolog (insulin aspart)	Odefsey (emtricitabine, rilpivirine, and
	tenofovir alafenamide)

Otezla (apremilast)	Ozempic (semaglutide)
Prezcobix (darunavir and cobicistat)	Prezista (darunavir)
Prolia (denosumab)	Repatha (evolocumab)
Rinvoq (upadacitinib)	Rybelsus (semaglutide)
Spiriva (tiotropium bromide)	Steglatro (ertugliflozin)
Stiolto Respimat (tiotropium bromide and	Symbicort (budesonide and formoterol
olodaterol)	fumarate dihydrate)
Symtuza (darunavir, cobicistat, emtricitabine,	Synjardy (empagliflozin and metformin
and tenofovir alafenamide)	hydrochloride)
Tivicay (dolutegravir)	Toujeo (insulin glargine)
Tradjenta (linagliptin)	Trelegy Ellipta (fluticasone furoate,
	umeclidinium, and vilanterol)
Tresiba (insulin degludec)	Triumeq (abacavir, dolutegravir, and
	lamivudine)
Trulicity (dulaglutide)	Truvada (emtricitabine and tenofovir
	disoproxil fumarate)
Ubrelvy (ubrogepant)	Victoza (liraglutide)
Vraylar (cariprazine)	Wegovy (semaglutide)
Xarelto (rivaroxaban)	Xifaxan (rifaximin)

This safety alert has been initiated due to compromised drug supply chain security and the impossibility of ensuring these drugs distributed by **AlphaMed Rx**, **Inc.** are not compromised. To clarify, this safety alert relates specifically to drugs distributed by **AlphaMed Rx**, **Inc.**, and not to the above-identified drugs generally. The Board has determined that circulation of this product poses significant risks to the public.

Immediately examine your inventory and quarantine suspicous product. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this safety alert. Your notification to your customers may be enhanced by including a copy of this notification letter.

If you identify adverse reactions, quality problems, or illegitimate product, please follow the FDA's guidance below as obtained from www.FDA.gov

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: <u>Download form</u> 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

Submit illegitimate product notifications through the 3911 platform in <u>CDER NextGen</u>, which is the agency's preferred method, or complete <u>Form FDA 3911</u> and submit via email. Trading partners should provide information:

• about the person or entity initiating the notification,

- the product that has been determined to be illegitimate and subject of the notification and
- a description of the circumstances surrounding the event that prompted the notification.

An illegitimate product is a product for which credible evidence shows the product:

- is counterfeit, diverted or stolen;
- is intentionally adulterated and would result in serious adverse health consequences or death;
- is the subject of a fraudulent transaction; or
- appears otherwise unfit for distribution and would be reasonably likely to result in serious adverse health consequences or death.

Visit the <u>Definitions of Suspect Product and Illegitimate Product for Verification Obligations</u>
<u>Under the Drug Supply Chain Security Act</u> guidance for more information.

We appreciate your assistance.

Georgia State Board of Pharmacy