

Drug Recall

DATE OF RECALL: September 14, 2022

DRUG NAME: CORRECTDOSE Products

RECALLING FIRM: Plastikon Healthcare LLC

REASON FOR RECALL: This recall was issued due to CGMP Deviations: The products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

FDA LINK: <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=194326>
<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=194325>
<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=194452>

OTHER DETAILS: See FDA Links

RECALLED PRODUCT:

Product Name	NDC #	Affected Lots
CORRECTDOSE Children's ALLERGY RELIEF (Diphenhydramine HCl 12.5 mg per 5 mL), 2.04 FL. OZ (60 mL) packaged in 12- 5mL individual doses	62320-0302-05	21011A Exp. 01/2023
CORRECTDOSE Children's PAIN RELIEF & Fever Reducer, Cherry, (Acetaminophen 160 mg per 5 mL), 2.04 FLOZ (60mL), packaged in 12-5mL individual doses	62320-0311-05	20096A Exp. 10/2022
CORRECTDOSE Children's COUGH & CHEST CONGESTION DM (Guaifenesin 100 mg / Dextromethorphan 5 mg per 5 mL) 2.04FL. OZ (60mL), packaged in 12-5 individual doses	62320-0321-05	21014A Exp. 02/2023