Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

14 NOV 2022

FDA ADVISORY
No. 2022-1892

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning on Substandard (Contaminated) Pediatric Drug Products in Syrup Dosage Form Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on eight (8) substandard (contaminated) pediatric drug products that have been identified in Indonesia in October 2022:

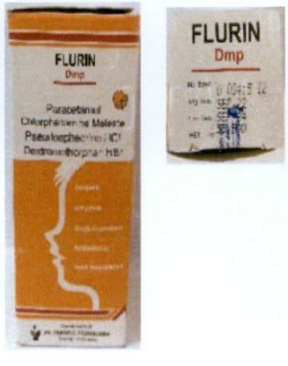
PRODUCT NAME	Paracetamol Syrup [Termorex]	Paracetamol + Chlorpheniramine Maleate + Pseudoephedrine HCl + Dextromethorphan Hbr Syrup [Flurin DMP]	Paracetamol + Guaifenesin + Chlorpheniramine Maleate Syrup [Unibebi Cough Syrup]
STATED MANUFACTURER	PT Konimex	PT Yarindo Farmatama	PT Universal Pharmaceutical Industries
BATCH NO.	AUG22A06	All batches	All batches
EXP. DATE	AUG 2025	N/A	N/A
PACKAGING LANGUAGE	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia
AVAILABLE PHOTO			

Figure 1. Termorex syrup, Flurin DMP syrup, and Unibebi Cough Syrup detected in Indonesia

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PRODUCT NAME	Paracetamol Syrup [Unibebi Demam Paracetamol Syrup]	Paracetamol Drops [Unibebi Demam Paracetamol Drops]	Paracetamol Drops
STATED MANUFACTURER	PT Universal Pharmaceutical Industries	PT Universal Pharmaceutical Industries	PT Afi Farma
BATCH NO.	All batches	All batches	All batches
EXP. DATE	N/A	N/A	N/A
PACKAGING LANGUAGE	Bahasa Indonesia	Bahasa Indonesia	Bahasa Indonesia
AVAILABLE PHOTO			

Figure 2. Unibebi Demam Paracetamol Syrup, Unibebi Fever Drops, and Paracetamol Drops detected in Indonesia

PRODUCT NAME	Paracetamol Syrup (mint)	Paracetamol + Guaifenesin + Chlorpheniramine Maleate Syrup [Vipcol Syrup]
STATED MANUFACTURER	PT Afi Farma	PT Afi Farma
BATCH NO.	All batches	All batches
EXP. DATE	N/A	N/A
PACKAGING LANGUAGE	Bahasa Indonesia	Bahasa Indonesia
AVAILABLE PHOTO		

Figure 3. Paracetamol syrup (mint) and Vipcol syrup detected in Indonesia

The FDA strongly advises the public to be vigilant on the circulation of these substandard drug products since its contaminants, Diethylene Glycol and Ethylene Glycol, are toxic to humans when consumed above the acceptable limit and may result to abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death. Substandard drug products are

products that fail to meet either their quality standards or specifications. To date, the Badan POM Indonesia ordered the concerned pharmaceutical industries to withdraw the drug syrups from circulation throughout Indonesia and destroy all the affected batches.

This is to emphasize that the abovementioned drug products are not registered with FDA. However, it is important to detect and remove these products from circulation to prevent harm to patients.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that these substandard drug products are not sold or not administered to patients in their localities or areas of jurisdiction. Furthermore, manufacturers of liquid dosage forms, especially syrups that contain excipients such as propylene glycol, polyethylene glycol, sorbitol, and/or glycerin/glycerol, are urged to test for the presence of the stated contaminants before use in production of pharmaceutical products.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale, or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

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Director General

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