December 10, 2021

URGENT: DRUG RECALL – ROMPE PECHO EX, CF, DM AND MAX LIQUIDS

RE:

Rompe Pecho DM

0-00856-00303-3	58593-275-06

Rompe Pecho CF

0-00856-33106-8	58593-235-06

Rompe Pecho EX

0-00856-30106-1	58593-829-06

Rompe Pecho Max

0-00856-00309-5	58593-828-08

Efficient Laboratories is expanding its voluntary nationwide recall to consumers to include an additional twelve lots of Rompe Pecho CF, Rompe Pecho EX, Rompe Pecho MAX, and Rompe Pecho DM due to microbial contamination concerns. These lots were distributed in 2019. To date, Efficient Laboratories has not received any reports of adverse events.

In rare circumstances, consumption of these specific lots could result in illness. These products are used to treat symptoms of the flu and the common cold, and each are packaged in a box containing a bottle of the liquid product. The affected twelve lots of Rompe Pecho product are contained in the chart below:

Rompe Pecho CF **Lots: 19F88 (Exp. Jun. 2022)** **19G164 (Exp. Jul. 2022)**
Rompe Pecho DM **Lots: 19F168 (Exp. Jun. 2022),** **19G145 (Exp. Jul. 2022), 19G361 (Exp. Jul. 2022), 19G449 (Exp. Jul. 2022),** **19G491 (Exp. Jul. 2022)**
Rompe Pecho EX **Lots: 19H20 (Exp. Aug. 2022), 19J98 (Exp. Sep. 2022), 19A418 (Exp. Jan. 2022),** **19E411 (Exp. May 2022)**
Rompe Pecho MAX **Lot: 19G219 (Exp. Jul. 2022)**

Efficient Laboratories has notified its distributors that bought these 12 lots. All distributors that bought these lots have confirmed there is no product in their inventory. In addition, a review of certain stores confirmed no inventory at the retail level as well.

Consumers that have Rompe Pecho EX, Rompe Pecho CF, Rompe Pecho DM, or Rompe Pecho MAX from these lots that are being recalled should stop using these products and discard them.

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

Please respond to this email with the following information:

Please check ALL appropriate boxes.

_____ I have read and understand the recall instructions provided in this December 10, 2021, letter.

_____ I have checked my stock and have quarantined inventory consisting of _____ units.

Indicate disposition of recalled product:

_____ Returned (Specify quantity, date and method)/held for return; _____
_____ Destroyed (Specify quantity, date and method); _____

Any adverse events associated with recalled product _____ Yes _____ No

If yes, please explain _____

Please check appropriate box(es) to describe your business

_____	Wholesales/distributor	_____	Retailer
_____	Pharmacy – retail	_____	Hospital/medical facility
_____	Hospital pharmacy	_____	Medical laboratory
_____	Physician's Office	_____	Other _____

Name: _____

Title: _____

Email: _____

Tel. Number: _____

Company Name: _____

Address: _____

City/State: _____

We appreciate your assistance.

Sincerely,

Miguel Reyes,
President
Efficient Laboratories, Inc.