February 2020 **COM-2020-008**

RECALL NOTIFICATION

DATE:
January 31, 2020

DRUG NAME:
Rompe Pecho EX, Rompe Pecho CF, and Rompe Pecho MAX liquid

COMPANY:
Efficient Laboratories, Inc.

REASON:
Microbial Contamination

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected product:

Product description	Lot #	Expiration date
Rompe Pecho EX	19F332	June 2022
Rompe Pecho CF	19H359	August 2022
Rompe Pecho MAX	19B42	February 2022

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Advise consumers to stop using, return, and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.

Contact information:

- Consumers:
  - Efficient Laboratories:
    - Phone: (305)-805-3456, Monday through Friday between 9:00 AM and 4:30 PM EST

Safety Note:

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

Additional information // Reference:

- Center for Drug Evaluation and Research. (2020, January 31). Efficient Laboratories, Inc. Issues Voluntary Nationwide Recall of Rompe Pecho EX, Rompe Pecho CF, and Rompe Pecho MAX due to Microbial Contamination. Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/efficient-laboratories-inc-issues-voluntary-nationwide-recall-rompe-pecho-ex-rompe-pecho-cf-and

Best regards,

PharmPix Clinical Department

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