February 2020 **COM-2020-010**

RECALL NOTIFICATION

DATE:
February 21, 2020

DRUG NAME:
Phenytoin Oral Suspension USP, 125 mg/5 mL

COMPANY:
Taro Pharmaceuticals U.S.A., Inc.

REASON:
Possible underdosing or overdosing after shaking before administration

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:

NDC	Product description	Lot #	Expiration date
51672-4069-01	**Phenytoin Oral Suspension USP, 125 mg/5 mL**	327874, 327876	December 2020

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug 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:

- Retail customers: Should follow the return process of any unsold unit as per letter sent to them by Taro Pharmaceuticals.
- Consumers:
  - Taro: Phone: 1-866-705-1553, Monday - Friday 7:00 am and 7:00 pm, U.S. Central Time. E-mail: TaroPVUS@taro.com

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, F. D. A. (2020, February 21). Taro Pharmaceuticals U.S.A. Issues Voluntary Nationwide Recall of Phenytoin Oral Suspension USP, 125 mg/5ml Due to Possible Underdosing or Overdosing. Retrieved from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-phenytoin-oral-suspension-usp-125-mg5ml?utm_campaign=FDA%20MedWatch%20-%20Phenytoin%20Oral%20Suspension%20USP%2C%20125%20mg%2F5%20mL%20by%20Taro%20Pharmaceuticals%3A%20Recall&utm_medium=email&utm_source=Eloqua

Best regards,

PharmPix Clinical Department

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