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Taro Pharmaceuticals issues recall of phenytoin oral suspension

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This recall is being conducted with the knowledge of the FDA

Taro Pharmaceuticals U.S.A., Inc. (“Taro” or the “Company”) is voluntarily recalling two (2) lots of Phenytoin Oral Suspension USP, 125 mg/5 mL both in 237 mL bottles, to the consumer level. Phenytoin Oral Suspension USP, 125 mg/5 mL is indicated for the treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures and is packaged in amber plastic bottles with an inner seal and a white child proof closure, and each bottle contains 237 mL. The reason for the recall is that product from these two lots of Phenytoin Oral Suspension may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing. This recall is being conducted with the knowledge of the FDA.

The population at risk is primarily infants and young children. In those patients, there is a reasonable probability that inaccurate dosing might result in a serious adverse effect such as intoxication or breakthrough seizures requiring medical intervention. For a small minority of patients, who might have severe or repeated breakthrough seizures, a drop in their phenytoin blood levels could result in life-threatening status epilepticus requiring immediate emergency room treatment. To date, Taro has not received any adverse event reports related to this recall.

The two (2) lots that are being recalled are as follows:

Lot #:	**Expiration Date:**
327874	December 2020
327876	December 2020

Each bottle is labeled to indicate the name of the product, Phenytoin Oral Suspension USP, 125 mg/5 mL and the NDC #51672-4069-1 (see image of container label below).

Lot 327874 was distributed to wholesale distributors, long-term care providers, a repackager and mail order customers in the U.S. market between May 3 and July 5, 2019. Lot 327876 was distributed to wholesale distributors, long-term care providers and mail order customers in the U.S. market between July 1 and August 21, 2019. These customers may have further distributed these lots to retail pharmacies for prescription dispensing to patients who were prescribed Phenytoin Oral

Suspension.

Taro is notifying its distributors and retail customers by phone, e-mail, and letters via U.S. Mail and is arranging for return of any containers or quantities of Phenytoin Oral Suspension Lots # 327874 and 327876 (both with an expiration date of December 2020). Retail customers that have any quantities of these two (2) lots which are being recalled, should stop distribution and return any unsold units to their wholesaler.

Consumers with questions regarding this recall can contact Taro by calling 1-866-705-1553 or by e-mail at TaroPVUS@taro.com, Monday through Friday between 7:00 am and 7:00 pm, U.S. Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.