EDDIE BAZA CALVO GOVERNOR **RAY TENORIO** LIEUTENANT GOVERNOR

GOVERNMENT OF GUAM DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT



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PRESS RELEASE **2017-** 043

Standard Homeopathic Company Issues Nationwide Recall of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets Due to Mislabeling

The Department of Public Health and Social Services, in coordination with the U.S. Food & Drug Administration, would like to inform the public of a nationwide recall involving all lots of Standard Homeopathic Company's Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets. The U.S. Food & Drug Administration (FDA) has concluded that the medicines have been found to contain inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the products' labels.

The recall includes the following products listed below:

Product	UPC Number
Hyland's Baby Teething Tablets	3-54973-31271-5
Hyland's Baby Teething Tablets	3-54973-31371-2
Hyland's Baby Teething Tablets	3-54973-31481-8
Hyland's Baby Teething Tablets	3-54973-31273-9
Hyland's Baby Teething Tablets	3-54973-31272-2
Hyland's Baby Teething Tablets	3-54973-31521-1
Hyland's Baby Nighttime Teething Tablets	3-54973-31971-4

FDA believes that belladonna represents a serious health hazard to children and that the effects of belladonna are unpredictable and has stated to the Company, "There is no known safe dose or toxic dose of belladonna in children because of the many factors that affect it."

The Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets were used to provide temporary relief of teething symptoms in children. The recall includes all products that retailers may have had in stock. The Company stopped making and shipping the medicines nationwide in October 2016. This recall ensures the removal of any possible remaining products that may be on store shelves. No other Standard Homeopathic Company/Hyland's products are affected by this recall.

To date, the Division of Environmental Health has determined that one affected product (Hyland's Baby Teething Tablets, UPC 3-54973-31271-5) was located and removed from K-mart in Tamuning. K-mart has confirmed that fifteen implicated products have been sold.

The Department has not received any local report of injuries or illnesses associated with the use of these recalled commodities. Consumers who are in possession of the items listed above are urged to refrain from use and return it to the place of purchase.

For any questions, please contact the Consumer Commodities Program at the Division of Environmental Health at 735-7221.

AMES W. GILL

Directo