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SUBJECT: ALFOODACT 2017-029 - Standard Homeopathic Company Issues Nationwide Recall of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets Due to Mislabeling

Date Issued: 14 April 2017

1. REFERENCES:

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

2. Background: Standard Homeopathic Company is recalling all lots of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets sold in retail stores to the consumer level. 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.

FDA believes that belladonna represents a serious health hazard to children and that the effects of belladonna are unpredictable. The Agency 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.

"We initiated this recall even after discontinuing production last fall because it is appropriate to do what our regulating agency has formally requested," said J.P. Borneman, PhD, chairman and CEO of Standard Homeopathic Company. "We are committed to maintaining and earning the trust consumers have placed in Standard Homeopathic Company. We have worked for 114 years to build relationships with our consumers. We intend to preserve that tradition of trust."

Standard Homeopathic Company is notifying its distributors and retailers by mail and is arranging for the return of all recalled products. Consumers who have products which are being recalled should discard the product.

Consumers with questions regarding this recall can contact Standard Homeopathic Company by calling 1-800-991-3376 (Monday-Friday 6 a.m. to 4 p.m. Pacific Time). Consumers should contact their physician or healthcare provider if they believe 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 these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report 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.
- Recall contact information: Consumers - Standard Homeopathic Company 1-800-991-3376; Media - Mary C. Borneman 424-224-4135.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

4. Product Affected/Product Photos:

UPC 3-54973-31271-5
UPC 3-54973-31371-2
UPC 3-54973-31481-8

UPC 3-54973-31273-9

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UPC 3-54973-31272-2
UPC 3-54973-31521-1

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UPC 3-54973-31971-4

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5. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:
a. Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use.

6. POSITIVE AND NEGATIVE FINDINGS:

a. Army and Air Force Public Health personnel, report your negative and positive findings HERE.

b. Defense Logistics Agency (DLA) Contractors, report positive and negative findings to your Accountable Officer.

c. AAFES, MWR, NEX, MCCS, and DeCA agencies, report your findings in accordance with the procedures outlined by your agency.

d. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 (For instructions on how to "Properly Prepare a Standard Form" (SF) 364 please use this link: [http://www.dla.mil/LandandMaritime/Offers/Services/TechnicalSupport/Logistics/Packaging/PrepareSF364.aspx]) and forward to your supporting NAVSUP Fleet Logistics Center (NAVSUP FLC) and copy furnished to NAVSUP 51. Your supporting NAVSUP FLC should forward to the account manager at DLA Troop Support. The form should include the number of the recall authorizing the survey action. Home-ported ships/galleys will utilize DD form 1149 to transfer with reimbursement to the PV. The PV will submit credit invoice to the account manager at DLA Troop Support.

7. The Point of Contact for this ALFOODACT message is CW4 Jemme Neal, Consumer Safety Officer at DLA-FTW. VOICE, DSN: 444-2922, Commercial (215) 737-2922 or email: dscpconssafofc@dla.mil.

8. Individuals or groups that would like to BEGIN receiving recall messages electronically can submit request HERE.

9. To STOP receiving recall messages, submit your request HERE.

10. Previous recalls and frequently asked questions are available at the following web site: http://www.dla.mil/TroopSupport/Subsistence/FoodSafety/fso/ALFOODACT.aspx.

//Signed//
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