



## Ohio Department of Agriculture and Ohio Department of Health



**Governor** Ted Strickland  
**Lieutenant Governor** Lee Fisher

**ODA Director** Robert J. Boggs  
**ODH Director** Alvin D. Jackson, M.D.

**TO:** Health Commissioners, Directors of Environmental Health and Interested Parties

**Subject:** Recall Announcement (ODA/ODH) 2010-93

**Date:** October 25, 2010

### **Working with FDA, Standard Homeopathic Company Voluntarily Recalls Hyland's Teething Tablets to Address Manufacturing Process**

Standard Homeopathic Company, in consultation with the U.S. Food and Drug Administration (FDA), is voluntarily recalling its Hyland's Teething Tablets. The company is initiating this recall in an abundance of caution due to an FDA investigation of its manufacturing facility. Hyland's Teething Tablets are manufactured in the United States and distributed throughout North America.

The Hyland's Teething Tablets UPC codes included in the recall are:

1. Hyland's Teething Tablets, 125 tablets, UPC # 3 54973 75041
2. Hyland's Teething Tablets, 250 tablets, UPC # 3 54973 75042
3. Hyland's Teething Tablets, 125 tablets, UPC # 3 54973 75066
4. Hyland's Teething Tablets, 50 tablets, UPC # 3 54973 75044
5. Hyland's Teething Tablets, 145 tablets, UPC # 3 54973 75121
6. Hyland's Teething Tablets, Clip Strip 6x125 tablets, UPC # 3 54973 35109

Adverse events have been reported but the FDA has said that a conclusive link to Teething Tablets has not been determined. The company, in working with the FDA, has identified manufacturing processes of Teething Tablets that can be improved to ensure uniformity in dosage. As a homeopathic product, Hyland's Teething Tablets have a wide margin of safety that protects consumers from harm.

After in-depth analysis, a comprehensive review of the company's adverse event report log, and more than 85 years of safe usage, the company is confident that Hyland's Teething Tablets are safe for infants and toddlers.

In addition to the product recall, Standard Homeopathic Company is refining its production, packaging and testing protocols. Throughout the process, Standard Homeopathic Company will continue to closely monitor and evaluate the situation and consult with FDA.

Consumers that are concerned about the safety of the product may contact Standard Homeopathic Company for instructions on a refund or replacement product. For these instructions or information regarding how to return or dispose of the product, consumers should log on to [www.hylandsteething.com/recall](http://www.hylandsteething.com/recall)<sup>9</sup> or call 1-877-496-5044 (Monday-Friday 8 a.m. to 10 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time).

"We initiated this voluntary recall to ensure our consumers know that their families' safety and health are our top priorities," said Mark Phillips, PharmD, President and Chief Pharmacist of Standard Homeopathic Company. "We are committed to maintaining and deserving the trust they have placed in Hyland's. We have worked for 107 years to build relationships with our consumers. We intend to preserve that tradition of trust."

Hyland's Teething Tablets is a homeopathic product intended to provide temporary relief of teething symptoms in children that is sold over-the-counter (OTC) in retail outlets.

Consumers who have medical concerns or questions should contact their healthcare provider. Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)<sup>10</sup>.

With over 100 years of experience in providing families with access to safe, natural, reliable medicines, Standard Homeopathic Company and its division, Hyland's, Inc., have many symptom fighting products consumers have come to trust. For more information on their line of products, visit [www.hylands.com](http://www.hylands.com)<sup>11</sup> or [www.facebook.com/Hylands.Health](http://www.facebook.com/Hylands.Health).

### **About Standard Homeopathic Company**

Standard Homeopathic Company develops and manufactures lines of homeopathic medicines, including its top-selling Hyland's brand. Hyland's homeopathic formulas are manufactured with the highest quality natural ingredients following the strictest standards of preparation. With over a century of commitment, Standard Homeopathic Company's tradition of excellence consistently provides quality and integrity in every product. From Hyland's Teething Tablets to Hyland's Calms Forté, Standard Homeopathic Company cares for your family at every stage of life. Consumers can trust Standard Homeopathic Company's products to be natural, gentle, effective and safe for the entire family.