



- URGENT - Recall of Hyland's Teething Tablets – ALL LOTS

Date: October 26, 2010

To : Hyland's Teething Tablets Distributors and Retailers

Name of Product : Hyland's Teething Tablets, 125 tablets, all lots
DIN 01956485 (as per label)

Hazard associated with the product: Unacceptable Risk

Reason: Hyland's Homeopathic Canada, a division of Standard Homeopathic Company, 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.

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.

Adverse events have been reported to the U.S. Food and Drug Administration (FDA) and to the company but conclusive links have not been formally determined; stakeholders consider that prudence is suitable. The company, in working with the US regulators, has identified manufacturing processes of Teething Tablets that can be improved to ensure greater uniformity in dosage of the Belladonna 3X ingredient. As a homeopathic product, Hyland's Teething Tablets have a wide margin of safety that normally 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.

"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.

No other Hyland's Homeopathic Canada or Standard Homeopathic Company products are affected by this recall.

381 Route 139N, Sutton, Qc J0E 2K0
☎ 450.538.6636 / 800.363.8933 📠 450.538.6638

Action items, steps to follow:

1. PLEASE IMMEDIATELY STOP ALL SALE OR DISTRIBUTION OF ALL TEETHING TABLETS, ALL LOTS.

★ **IMPORTANT: If you are a distributor**, you also need to inform your customers of this recall in order for them to return all lots of the product to the address below.

2. Conduct an inventory assessment using the fax form attached

3. Return the completed fax form before or by Monday November 1, 2010 to the attention of: Troy Walker, fax 450.538.6638

4. Return all stock of Hyland's Teething Tablets, all lots, to the address below:

Stericycle
25 Ironside Crescent
Toronto, Ontario
M1X 1G5

★ **Reference: Event 2265** (for Retailers/Distributors)

5. Ship through Purolator (1.888.744.7123) and charge it to account #1481538 (Hyland's Homeopathic Canada)

6. Insert a copy of the fax form. ★ IMPORTANT: This is the only way you can be reimbursed.

Health Canada has been contacted concerning this recall.

Your immediate attention to the above instructions is required.

Thank you for your cooperation and assistance. Please do not hesitate to contact us should you require further information.

Sincerely,

Hyland's Homeopathic Canada Inc.

Attach.



- URGENT FAX -
NATURAL HEALTH PRODUCT RECALL
Fax: 450.538.6638 or 450.988.1180
Or email it: recall@hylands.ca

Product: Hyland's Teething Tablets, 125 Tablets, all lots DIN 01956485 (as per label)

Please return by November 1, 2010 to Troy Walker, Customer Service Centre.

Please indicate the amount of product per lot you currently have in stock. If no stock on hand, mark "0" beside each lot. A follow-up contact will be made if you do not reply by November 1, 2010.

Product Name	Size	Lot	Quantity in Stock
Teething Tablets	125 Tablets		
Teething Tablets	125 Tablets		
Teething Tablets	125 Tablets		
Teething Tablets	125 Tablets		

Customer Name & Address

Store / Distributor Name	
Customer Name	
Address	
City	
Province	
Postal Code	
Telephone number	
Signature of authorized person	
Printed name of authorized person	
Date	

Please return all lots of this product to the address below

★ **IMPORTANT: Insert a copy of this form.** This is the only way you can be reimbursed.

Ship through Purolator (1.888.744.7123) and charge account #1481538 (Hyland's Homeopathic Canada)

Stericycle
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 Toronto, Ontario
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Retail/Distributors – Event 2265

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