Hyland's Teething Tablets: Questions and Answers

What action is FDA taking?

On October 23, 2010, the Food and Drug Administration (FDA) warned consumers to stop using and discard Hyland's Teething Tablets. The manufacturer is recalling this product.

Why is FDA taking this action?

FDA is issuing this warning because the use of Hyland's Teething Tablets may pose a risk to children. FDA analysis and testing identified some Hyland's Teething Tablets that contained varying amounts of belladonna, a potentially toxic ingredient. FDA has received reports of serious adverse events in children taking this product that are consistent with belladonna toxicity. An ongoing FDA inspection at the manufacturer indicates substandard control of the manufacturing operation.

FDA has also received reports of children who consumed more tablets than recommended, because the containers do not have child resistant caps.

What product is affected by this warning?

FDA is warning consumers about all lots of Hyland's Teething Tablets. This product is widely sold in pharmacies, other retail stores, and on the Internet as an over-the-counter (OTC) homeopathic drug intended to provide temporary relief of symptoms related to teething in children.

What is belladonna?

Belladonna is commonly known as Deadly Nightshade. It is a plant whose leaves and berries are extremely toxic. Belladonna has been used as both a poison and a medicine throughout history.

What are symptoms of belladonna toxicity or overdose?

Belladonna alkaloids have anticholinergic effects. Classic signs of anticholinergic toxicity include fast heart rate, increased body temperature, dry skin and dry mouth, skin flushing, constipation, decreased urination, agitation, disorientation, hallucinations, and dilated pupils. Drowsiness may also be seen in infants.

Are Hyland's Teething Tablets approved by the FDA?

FDA has not evaluated Hyland's Teething Tablets for safety or efficacy, and is not aware of any proven clinical benefit offered by the product.

What should consumers do if they experience harm related to these products?

FDA recommends that consumers contact their health care professional if their child experiences symptoms after taking Hyland's Teething Tablets. Symptoms include a depressed level of consciousness, seizure, difficulty or slowed breathing, lethargy, sleepiness, muscle weakness, skin flushing, constipation, difficulty urinating, or agitation.

Health care professionals and consumers should report side effects from use of Hyland's teething tablets to FDA through the MedWatch program, by phone at 1-800-332-1088, or online at *www.fda.gov/medwatch/index.html*.

What steps is the FDA taking?

FDA issued a consumer advisory warning consumers to stop using and discard or return the Hyland's Teething Tablet product. The agency's investigation of the product and the firm's manufacturing operations is ongoing.

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