Indiana State Department of Health
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Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: May 12, 2010

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: FDA Benadryl Product Advisory

SUGGESTED ACTION: **Public Advisory; Benadryl Extra Strength Itch Stopping Gel; Recommend notification of affected stores via phone, fax or e-mail.**

Information is being provided in case of consumer inquiry.

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FDA PRESS RELEASE

For Immediate Release: May 12, 2010
Media Inquiries: Shelly Burgess, 301-796-4651, shelly.burgess@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA: Serious Side Effects from Swallowing Topical Benadryl Product

The U.S. Food and Drug Administration is warning consumers about potentially serious side effects from mistakenly swallowing Benadryl Extra Strength Itch Stopping Gel, an over-the-counter (OTC) product that should only be used on the skin.

The FDA has received reports of serious side effects in people who have mistakenly swallowed the product. Some OTC Benadryl products are intended to be swallowed. However, Benadryl Extra Strength Itch Stopping Gel is only safe and effective when used, as directed, on the skin. People swallowing the gel can ingest a dangerous amount of the active ingredient, diphenhydramine. Large doses of diphenhydramine can result in serious side effects such as unconsciousness, hallucinations, and confusion.

"Consumer confusion and incorrect product use are serious public health issues," said Carol Holquist, R.Ph., director of FDA's Division of Medication Error Prevention and Analysis. "FDA is advising consumers and pharmacies to store products for the skin separately from products that should be swallowed."

Many pharmacies and grocery stores sell diphenhydramine topical gels that look very similar in packaging to Benadryl Extra Strength Itch Stopping Gel. It is important that consumers also avoid swallowing these products.

To help consumers recognize that Benadryl Extra Strength Itch Stopping Gel is meant for use on the skin, the manufacturer, Johnson and Johnson, has taken the following actions:

- Changed the product label to add a new, prominent statement "For Skin Use Only."
- Attached a sticker to the cap of the product that says "For Skin Use Only."
- Initiated consumer studies to better understand factors that may contribute to consumers mistakenly swallowing Benadryl Extra Strength Itch Stopping Gel.

The FDA encourages manufacturers of similar products to adopt similar changes to their labeling and packaging.

The repackaged product is currently stocked in retail stores. The FDA reminds consumers and health care professionals to always read the "Drug Facts" box to identify active ingredients, directions for use, and warnings before using any OTC drug product.

Consumers and health care professionals are encouraged to report adverse side effects to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch or by calling 800-332-1088.

For more information

FDA 101: Medication Errors
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048644.htm

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