Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

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

DATE: March 29, 2011

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

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

SUBJECT: FDA Advisory to Stop Using Soladek Vitamin Solution

SUGGESTED ACTION: **Information provided in case of customer inquiry about Soladek Vitamin Solution**

****

FDA Warns Consumers to Stop Using Soladek Vitamin Solution

Risk of serious health problems from dangerously high levels of vitamins A and D

The U.S. Food and Drug Administration is warning consumers to stop using Soladek, a vitamin-solution product marketed by Indo Pharma, S.A., of the Dominican Republic, because the product may contain dangerously high levels of vitamins A and D.

Soladek is marketed with claims that the product treats "hypo and avitaminosis, rickets, growth, dentition, lactation, fractures, infection, convalescence, protection and regeneration of certain epithelium (bronchial, glandular, ocular, cutaneous), corticotherapy, aging and pregnancy." The product is sold in a box labeled in Spanish and containing a vial of the solution.

FDA recently received information that tested samples of Soladek contained levels of vitamin A and vitamin D that were many times the recommended daily allowances for these vitamins. Intake of excessively high levels of these vitamins poses a risk to human health.

The FDA also received seven reports of serious health problems occurring in consumers using the product. The problems include decreased renal function, elevated levels of calcium in the blood, fatigue, heart arrhythmia, vomiting, and diarrhea.

Symptoms of vitamin D toxicity include weakness, fatigue, headache, nausea, vomiting, diarrhea, changes in mental status, increased blood pressure, abnormal heart rate or rhythm, kidney damage, and coma.

Symptoms of vitamin A toxicity include anemia, anorexia, alopecia, joint pain, bone weakness, bulging eyes, liver abnormalities, and birth defects.

Consumers who are in possession of Soladek should stop using the product immediately. Any consumers who have been using Soladek and are experiencing any of the above symptoms should see a doctor immediately.

Soladek cannot currently be marketed legally in the United States because U.S. law prohibits the sale of products claiming to treat disease conditions without review and approval by the FDA. However, the reports of adverse events and other information leads the FDA to conclude that Soladek may be available illegally in the country; therefore, the agency is issuing this warning.

Health care professionals and consumers should report adverse events or other problems with regulated products to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax, or phone.

- **Online**: https://www.accessdata.fda.gov/scripts/medwatch.
- **Regular Mail**: Use FDA postage paid form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax**: 800-FDA-0178
- **Phone**: 800-FDA-1088

#