Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 3, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Solace International, Inc. – RECALL [Drug]

AFFECTED PRODUCT: **Dermatend Original and Dermatend Ultra, in all sizes and dosage form.**

SUMMARY: **Unclassified Recall; The recall has been initiated because Dermatend is not FDA approved, thus has not been shown to be safe and effective for the uses suggested in the labeling. Using these Dermatend products instead of seeking medical attention could result in delayed diagnosis of conditions such as cancer.**

Dermatend Original and Dermatend Ultra are packaged in a flexible plastic tubes labeled with the product name in blue letters. All units and lots are affected by the recall.

This product was sold nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Solace International, Inc. at 775-323-1413 or info@dermatend.com, Monday through Friday from 8:00 a.m. to 5:00 p.m. PST.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Solace International, Inc. Issues Voluntary Nationwide Recall of Dermatend Original and Dermatend Ultra Due to Safety Concerns

Contact:
Consumer:
775-323-1413

Media:
Aaron Lilly
775-323-1413

FOR IMMEDIATE RELEASE - August 28, 2014 - Reno, Nevada, Solace International, Inc. is voluntarily recalling all lots of Dermatend Original and Dermatend Ultra, in all sizes and dosage form, to the distributor/wholesaler level. A mole should be removed under the supervision of a dermatologist. Dermatend is not FDA approved, thus has not been shown to be safe and effective for the uses suggested in the labeling. Using these Dermatend products instead of seeking medical attention could result in delayed diagnosis of conditions such as cancer.

Currently, the Dermatend Original and Dermatend Ultra products are used to remove moles, warts and skin tags. Dermatend Original and Dermatend Ultra are packaged in a flexible plastic tubes labeled with the product name in blue letters. All units and lots are affected by the recall.

Solace International, Inc. is notifying its distributors/wholesalers by certified letter and is arranging for the return of all recalled products. Distributors/wholesalers that have Dermatend Original and Dermatend Ultra product, which is being recalled, should return all units and cases to Solace International, Inc. Consumers who purchased Dermatend Original and Dermatend Ultra to remove moles and warts should immediately discontinue use and consult their physician.

Consumers with questions regarding this recall can contact Solace International, Inc. at 775-323-1413 or info@dermatend.com, Monday through Friday from 8:00 a.m. to 5:00 p.m. PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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