Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: June 10, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

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

ASG

SUBJECT: FDA Warns Consumers Not to Use Skin Products Made by Clarcon Due to Bacterial Contamination Risk

Suggested Action: **FDA Advisory; FDA is warning consumers to not use any Clarcon products; Recommend notification to establishments that may carry these products via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The U.S. Food and Drug Administration announced today that Clarcon Biological Chemistry Laboratory Inc. of Roy, Utah, is voluntarily recalling some skin sanitizers and skin protectants marketed under several different brand names because of high levels of disease-causing bacteria found in the product during a recent inspection. Detail information is not available at this time. Please notify this office at 317-233-7360 if any recalled product is found.

FDA NEWS RELEASE

For Immediate Release: June 8, 2009

Media Inquiries: Siobhan DeLancey, 301-796-4668, siobhan.delancey@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Warns Consumers Not to Use Skin Products Made by Clarcon Due to Bacterial Contamination Risk

Products marketed under various names

The U.S. Food and Drug Administration announced today that Clarcon Biological Chemistry Laboratory Inc. of Roy, Utah, is voluntarily recalling some skin sanitizers and skin protectants marketed under several different brand names because of high levels of disease-causing bacteria found in the product during a recent inspection. The FDA is warning consumers to not use any Clarcon products.

Consumers should not use any Clarcon products and should throw these products away in household refuse. Analyses of several samples of over-the-counter topical antimicrobial skin sanitizer and skin protectant products revealed high levels of various bacteria, including some associated with unsanitary conditions. Some of these bacteria can cause opportunistic infections of the skin and underlying tissues. Such infections may need medical or surgical attention, and may result in permanent damage. Examples of products that should be discarded include:

Citrushield Lotion

Dermasentials DermaBarrier

Dermassentials by Clarcon Antimicrobial Hand Sanitizer

Iron Fist Barrier Hand Treatment

Skin Shield Restaurant

Skin Shield Industrial

Skin Shield Beauty Salon Lotion

Total Skin Care Beauty

Total Skin Care Work

Findings from the FDA's recent inspection of the Clarcon facility are particularly concerning because the products are promoted as antimicrobial agents that claim to treat open wounds, damaged skin, and protect against various infectious diseases. The inspection uncovered serious deviations from FDA's current Good Manufacturing Practice requirements.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

--Online
--Regular Mail: use postage-paid FDA form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
--Fax: 800-FDA-0178
--Phone: 800-FDA-1088

For more information:
Consumer article
Photos: Product Labels

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