Mitchell E. Daniels, Jr.
Governor

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

Indiana State Department of Health

An Equal Opportunity Employer

DATE: September 8, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

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

SUBJECT: FDA News Release Unapproved Antimicrobial Products

Suggested Action: Unclassified Recall; Care-Tech Laboratories Agrees to Stop Making, Selling and Distributing Unapproved Antimicrobial Products; This information is being provided for Consumer Inquiry.

From the information provided by FDA, Care-Tech products are sold online and through telephone orders to hospitals, nursing homes and other health care facilities. They are not sold in retail stores.

FDA News Release

For Immediate Release: Sept. 8, 2009

Media Inquires: Christopher Kelly, 301-796-4676, christopherkelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

Care-Tech Laboratories Agrees to Stop Making, Selling and Distributing Unapproved Antimicrobial Products

The U.S. Food and Drug Administration today announced that St. Louis-based Care-Tech Laboratories Inc. and its principal officers, John C. Brereton and Sherry L. Brereton, have signed a consent decree, agreeing to stop the illegal manufacture, marketing, and distribution of over-the-counter (OTC) antimicrobial drugs used to treat and prevent infection.

Inspectors found that Care-Tech violated numerous provisions of the FDA's current good manufacturing practice (cGMP) regulations that direct how antimicrobial drugs are made. Additionally, the products do not conform to any applicable regulations for OTC drug products and have not undergone an FDA review, and therefore are considered unapproved drug products.

Under the terms of the consent decree, Care-Tech may not resume manufacturing and distribution of the drugs until it corrects these and other violations.

"The FDA is concerned about Care-Tech's products because they lack FDA approval, do not conform to any applicable over-the-counter drug monograph, and are not appropriately manufactured," said Deborah Autor, director of the FDA's Office of Compliance, Center for Drug Evaluation and Research. "Companies have an obligation to consumers to ensure that their products are safe, effective, and high quality, and the FDA recommends that Care-Tech's customers seek alternative products."

Care-Tech products are sold online and through telephone orders to hospitals, nursing homes and other health care facilities. They are not sold in retail stores. The FDA is not aware of any reports of injury or illness related to the use of these products. Consumers should contact Care-Tech at 1-800-325-9681 to return products in their possession, which include:

Barri-Care
Care-Crème
Caricia Care
CC-500
Clinical Care
Consept
Formula Magic
Humatrix
Loving Lather
Loving Lather II
Loving Lotion
Orchid Fresh II
Satin
Tech 2000
Techni-Care
Urban Skin

Health care professionals and consumers may report serious adverse events (side effects) or quality problems for these or any products to the FDA's MedWatch Adverse Event Reporting program, online, or by regular mail, fax or phone.

- Online: http://www.fda.gov/Safety/MedWatch/default.htm
- Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 800-FDA-0178
- Phone: 800-FDA-1088

For more information:

Facts About Current Good Manufacturing Practices (cGMPs)
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm

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