North Carolina Department of Health and Human Services
Division of Health Service Regulation
Mental Health Licensure and Certification
2718 Mail Service Center • Raleigh, North Carolina 27699-2718
http://www.ncdhhs.gov/dhsr/

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Stephanie Alexander, Chief
Phone: 919-855-3795
Fax: 919-715-8078

NOTICE

TO: Licensed MH/DD/SAS Providers
RE: U.S. Food and Drug Administration Consumer Alert
DATE: June 11, 2009

Following is an announcement by the U. S. Food and Drug Administration (FDA) warning consumers of a tainted skin sanitizer. The Centers for Medicare & Medicaid Services (CMS) is advising health care providers and consumers not to use skin products made by Clarcon Biological Chemistry Laboratory. Clarcon 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.

Consumers and providers are being warned to not use any Clarcon products and to throw these products away in household refuse.

FDA analyses of several samples of Clarcon 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

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