



## FDA NEWS RELEASE

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### **FDA enters consent decree of permanent injunction against Florida drug companies** *Multiple violations prompt government action*

The U.S. Food and Drug Administration announced today that the District Court for the Middle District of Florida entered a consent decree that prohibits Hill Dermaceuticals, Inc., and Hill Labs, Inc. (collectively referred to as “Hill”), and individuals Jerry S. Roth and Rosario G. Ramirez, from introducing adulterated drugs into interstate commerce.

The government’s complaint in this action, filed by the U.S. Department of Justice on September 27, 2011, describes numerous deviations from current good manufacturing practice (cGMP) for drugs documented during the FDA’s inspections of Hill.

The drug cGMP regulations require manufacturers to control all aspects of the processes and procedures by which they manufacture drugs to prevent the production of unsafe or ineffective drug products.

The government further alleges that Hill has, on more than one occasion, submitted untrue statements in support of submissions to the FDA. These falsified submissions are evidence of persistent data integrity problems at Hill.

“Because this company continued to violate current good manufacturing practice regulations and falsify information on submissions to FDA, the agency took this action in an effort to protect consumers,” said Dara Corrigan, the FDA’s Associate Commissioner for Regulatory Affairs. “The FDA continues to be committed to protecting consumers from potentially unsafe products that may be offered on the market.”

The terms of the consent decree include provisions to prevent Hill from introducing adulterated drugs into interstate commerce. In addition, the decree includes elements of the FDA’s Application Integrity Policy, which is designed to ensure the authenticity of data submitted to the agency. The FDA will verify the adequacy of Hill’s corrective actions.

Hill manufactures the following topical prescription drug products: DermaSmoothe/FS Scalp Oil; Dermasmoothe/FS Body Oil; and DermOtic Oil Eardrops. In addition, Hill is the contract manufacturer of the topical prescription drug products Tri-Luma Cream and Capex Shampoo for Galderma Laboratories.

The FDA is not currently aware of any recent adverse events related to the use of any of Hill's products. Any such complaints of adverse events should be reported to the agency at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.

For more information:

Hill Warning Letters

[Warning Letter \(April 27, 2009\)](#)

[Warning Letter \(August 18, 2009\)](#)