



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35  
11/25/98

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Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

ORL-99-10

November 17, 1998

Frank Newman, President and CEO  
Eckerd Corporation  
P.O. Box 4689  
Clearwater, FL 33758

Dear Mr Newman:

During an inspection of your corporate headquarters in Largo, Florida on August 28 and 31, 1998, FDA Investigator Karen G. Hirshfield documented that Eckerd Corporation markets "Swimmer's EAR DROPS."

"Swimmer's EAR DROPS" is labeled to contain "Isopropyl Alcohol 97.25% and Boric Acid," and is labeled "For drying water clogged ears," "Dries Water in Ears caused by swimming, bathing & showering," and "Helps relieve ear discomfort from excess water in ears." The term swimmer's ear is defined in the medical literature to be otitis externa, an inflammation of the external auditory canal. Based on the trade name, "Swimmer's EAR DROPS" and its labeled indications, this product is subject to the final rule covering OTC Otic Drugs for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears published in the February 15, 1995 Federal Register, effective on August 15, 1995, and codified in 21 CFR 310.545(a)(15). This is a negative final rule and establishes that no ingredients are recognized as safe and effective for use in topical OTC drug products labeled for the prevention of swimmer's ear or the drying of water-clogged ears. The FDA, in the August 16, 1995 Federal Register, published a partial stay of the February 15, 1995 Final Rule. This stay is applicable only to topical otic drug products formulated with 95% isopropyl alcohol, 5% glycerin or anhydrous glycerin, and labeled for the drying of water-clogged ears.

Based on the "Swimmer's EAR DROPS" trade name, this product is intended to treat, mitigate, cure, or prevent "swimmer's ear," a term commonly used for otitis externa. The FDA expert panel reviewing otic drugs defines "swimmer's ear" as a "diffuse external otitis...an infection of the skin lining the external auditory canal." The FDA, in the February 15, 1995 Final Rule, concludes that the diagnosis and treatment of this infection by a physician is necessary, and found that no OTC drugs are generally recognized as safe and effective for this

indication. The FDA also states in this final rule that "At this time, there is a lack of data from adequate and well-controlled studies to establish that acetic acid, isopropyl alcohol, anhydrous glycerin, or any other ingredients are safe and effective for use as a topical otic drug product for the prevention of swimmer's (ear) or for drying water-clogged ears."

Based on the above, this product is a new drug [section 201(p) of the Act] which may not be legally marketed (section 505 of the Act) because no application has been approved for this product (section 505 of the Act). This product is misbranded [section 502(f)(1) of the Act] because its labeling fails to bear adequate directions for use.

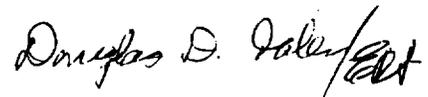
The list of violations above is not intended to be construed as all inclusive of those that exist at your firm. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may consider this information when awarding contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include a seizure and/or injunction.

Please respond to this office in writing, within fifteen (15) working days of the receipt of this letter, of specific actions you will take to correct the violations. Your response should include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Kendall W. Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen  
Director  
Florida District

cc: 