



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-36

m2544n

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 22, 1999

WARNING LETTER
CIN-WL-99-228

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kenneth D. Pings
Vice President, Product Development
Andrew Jergens Co.
2535 Spring Grove Avenue
Cincinnati, Ohio 45214

Dear Mr. Pings:

This letter concerns **Jergens Anti-Bacterial ANTISEPTIC LOTION** currently marketed by your firm for over-the-counter (OTC) drug uses. Based on information and labeling obtained during an inspection of your firm on December 17, 1998, this product contains benzalkonium chloride as its active "drug" ingredient. It is intended for repeated applications, to bond to, and remain on, the skin for continuous antimicrobial effectiveness and protection against pathogenic microorganisms. These representations are conveyed through labeling and promotional statements, which include: "**Long-Lasting.**" "**Germ Protection,**" "**Your skin needs daily protection from ...the bacteria and germs you encounter every day...**," "**...contains...the unique anti-bacterial BC-System...helping to reduce everyday germs that can cause infection and illness,**" "**...Reduce Germs On Contact,**" and "**...bonds to skin for germ protection.**"

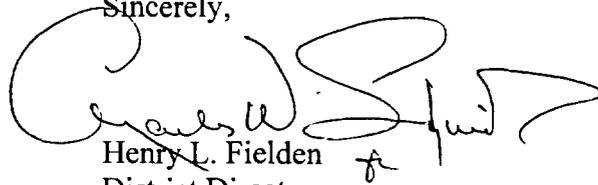
From a review of the information and labeling provided, we have determined that, as formulated and labeled, **Jergens Anti-Bacterial ANTISEPTIC LOTION** does not qualify for evaluation under the ongoing OTC Drug Review being conducted by the Food and Drug Administration (FDA). Also, this product is not exempt from the new drug application (NDA) provisions of the Federal Food, Drug and Cosmetic Act (Act). Representatives for prophylactic antimicrobial barrier use, as noted above, are not described in any of the rulemakings being considered under the Review. Further, we are not aware of any substantial scientific evidence that **Jergens Anti-Bacterial ANTISEPTIC LOTION** is generally recognized among scientific experts as safe and effective for these uses, and this product has not been marketed for a material time and to a material extent. Thus, **Jergens Anti-Bacterial ANTISEPTIC LOTION** is a "new drug" as defined by section 201(p) of the Act and it may not be legally marketed in the United States without an approved NDA under section 505(a) of the Act. In addition, since the adequacy of the labeled directions for these antimicrobial uses has not been determined, this product is misbranded under section 502(f)(1) of the Act.

The violations described above are not meant to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may consider this information when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. It should also 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 within which corrections will be completed. Your response should be addressed to Leonard J. Farr, Compliance Officer, at the above address.

Sincerely,



Henry L. Fielden
District Director