DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

HFD-310 REG File

WARNING LETTER

MAY 6 1998

Bristol-Meyers Squibb Co.
345 Park Avenue
New York, New York 10154

Ref: 98-HFD-312-02

Dear Mr.

This letter is in reference to **Keri Anti-Bacterial Hand Lotion** currently marketed by your firm. Based on information and labeling submitted by or on behalf of your firm on April 15, 1997 and April 8, 1998 and discussed during our meeting on April 20, 1998 with your firm's representatives, this product contains as its active "drug" ingredient, triclosan (0.3%). It is intended for repeated use on the hands by the general public and by health-care professionals as an "Antiseptic/Moisturizer" and to remain on the skin to provide hours of continuous antimicrobial effectiveness against pathogenic microorganisms. These representations are conveyed through labeling and promotional statements, which include "...To help reduce bacteria that potentially can cause disease...for repeated use...Leaves Hands Soft & Smooth While It Kills Germs...The first and only moisturizing lotion clinically proven to kill germs as it softens hands...you don't wash it off..."

After carefully reviewing the information and labeling provided, we have determined that, as formulated and labeled, **Keri Anti-Bacterial Hand Lotion** does not qualify for evaluation under the ongoing OTC Drug Review being conducted by the Food and Drug Administration (FDA), and this product is not exempt from the new drug application (NDA) provisions of the Federal Food, Drug, and Cosmetic Act (Act). Representations 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 **Keri Anti-Bacterial Hand 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, **Keri Anti-Bacterial Hand Lotion** is a "new drug" [section 201(p) of the Act] and may not be legally marketed in the United States without an approved NDA [section 505(a) of the Act]. And, 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 of the Act described above are not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of the

issuance of all warning letters about drugs and devices so that they may take this information into account 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. Your response 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 reply should be addressed to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857, Attention: Kevin M. Budich, Compliance Officer. If necessary, you may contact Mr. Budich by telephone at 1-301-594-1065.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and Nonprescription
Drug Compliance (HFD-310)
Office of Compliance
Center for Drug Evaluation and Research