



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

March 11, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 12

Douglas B. Murphy
President
Dental Resources, Inc.
530 River Street South
Delano, Minnesota 55328

Dear Mr. Murphy:

This letter is written in reference to the marketing of Home Care Stannous Gel (0.4% stannous fluoride gel) by your firm. The product is offered for use by children or adults who are caries prone, have orthodontic bands, have undergone irradiation, or who suffer from periodontal disease.

Based on the claims cited above, the product is a drug as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). The Food and Drug Administration evaluated 0.4% stannous fluoride treatment gels as part of the Over-the-Counter (OTC) Drug Review. Although such gels were formerly limited to prescription dispensing, the Agency concluded in a final regulation published in the October 6, 1995, Federal Register (60 FR 52474) that 0.4% stannous fluoride treatment gels are to be marketed as OTC drugs. These regulations are codified at Title 21, Code of Federal Regulations (21 CFR), Part 355.

Based on the above requirement that 0.4% stannous fluoride treatment gels must now be marketed as OTC drug products, your Home Care Stannous Gel is misbranded under Section 503(b)(4)(B) of the Act because it bears the statement "U.S. Federal Law Prohibits dispensing without a prescription."

The product is misbranded [Section 502(f)(1) of the Act] because it does not bear the directions for use as established in 21 CFR 355.50(d)(4). It is further misbranded [Section 502(f)(2) of the Act] for failure to bear the warnings required

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by 21 CFR 355.50(c). It is also misbranded [Section 502(a) of the Act] for failure to bear the additional labeling statements required by 21 CFR 355.50(e). The product is further misbranded in that it fails to declare the inactive ingredients as required by Section 502(e)(1)(A)(iii) of the Act.

OTC fluoride dental drug products subject to the final regulations at 21 CFR 355 are now required to be labeled in compliance with the Drug Facts Format regulations found at 21 CFR 201.66. Your product fails to comply with these regulations, and is therefore misbranded [Section 502(c) of the Act].

The above list of violations is not intended to be an all-inclusive list of deficiencies of products distributed by your firm. It is your responsibility to ensure that the drug products you distribute meet all the requirements of the Act and its implementing regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrections cannot be completed within 15 working days, state the reason for delay and the time frame within which corrections will be made.

Your reply should be addressed to Compliance Officer Brian D. Garthwaite, Ph.D., at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

BDG/ccl

BY