



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

12/30/97
752

Telephone (201) 331-2901

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

December 11, 1997

Warning Letter

RELEASE

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

William Stern, President
Woodstock Natural Products, Inc.
2337 Lemoine Avenue
Fort Lee, New Jersey 07024

REVIEWED BY Az 12/17/97
C.O. DATE

FILE NO.: 98-NWJ-08

Dear Mr. Stern:

This is in reference to "The Natural Dentist HERBAL MOUTH AND GUM THERAPY DAILY ORAL RINSE" and "The Natural Dentist Herbal Toothpaste and Gum Therapy" products which are marketed by your firm. According to the labeling, the rinse contains various herbal ingredients, glycerin, aloe and flavoring, and is offered to reduce and prevent swollen gums, to soothe bleeding gums and to help prevent gum problems, tooth decay, and minor mouth irritations. The label of the toothpaste lists sodium monofluorophosphate under the heading "active ingredient" and various herbs and other ingredients under the heading "ingredients." The labeling of the toothpaste bears claims that it will, among other things, prevent gingivitis.

In the FEDERAL REGISTER of September 19, 1990, (55 FR 38560), the agency published a "call for data" for ingredients in oral health care products bearing antiplaque and antiplaque related claims as part of the OTC Drug Review. The agency noted, on page 38562 of that document, that in order to be eligible for review under the OTC drug review procedures, the ingredient must have been marketed in a product with the relevant indication (e.g., with a plaque or gingivitis claim) to a material extent and for a material time. Manufacturers of products bearing antiplaque claims that have not been marketed in such a manner must submit supporting safety and effectiveness data prior to marketing their products. These products may not be legally marketed in interstate commerce until new drug applications are approved.

We are not aware of any evidence that the combinations of ingredients in "The Natural Dentist HERBAL MOUTH AND GUM THERAPY DAILY ORAL RINSE" and "The Natural Dentist Herbal Toothpaste and Gum Therapy" are generally recognized as safe and effective for

the claims made in their labeling, nor are we aware of any evidence that the combinations of ingredients have been marketed to a material extent and for a material time for the plaque/gingivitis related indications in the products' labeling. The products, as formulated and labeled, are not covered by the OTC Drug Review.

Based on the information cited above, we consider the products to be "new drugs" (Section 201(p) of the Act) which may not be marketed in the United States unless the products have approved New Drug Applications (as described in section 505(a)). The products are also misbranded (Section 502(f)(1) of the Act) because their labeling fails to bear adequate directions for use for the conditions for which they are offered.

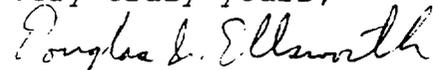
The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that the drug products you distribute are in compliance with the Act and regulations promulgated under it. Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. 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.

Please note that it is acceptable to market an anticaries toothpaste containing sodium monofluorophosphate as the active ingredient provided the formulation and labeling conform to the requirements of Title 21 Code of Federal Regulations part 355.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be made.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



Douglas I. Ellsworth
District Director
New Jersey District Office

AC:slw