



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g 3744d

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

WARNING LETTER

NWE-03-03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas M. Chapel, CEO
Tom's of Maine, Inc.
302 Lafayette Center
Kennebunk, ME 04043

Dear Mr. Chapel:

This letter is in reference to the marketing of the following products:

- "Natural Bronchial Syrup Adult Formula";
Examples of claims for this product include "to help loosen bronchial passages," "... gently stimulate the mucous membranes of the respiratory tract promoting clear and healthy bronchial passages," and "natural anise oil contributes vaporizing actions, helping to activate the swallowing reflex which can lessen a tickle sensation in the throat"
- "Natural Bronchial Syrup Children's Formula";
Examples of claims for this product include "to help loosen bronchial passages" and "... gently stimulate the mucous membranes of the respiratory tract promoting clear and healthy bronchial passages"
- "Natural Nasal Decongestant Children's Nighttime Cold Formula";
- "Natural Nasal Decongestant Children's Daytime Cold Formula";
- "Natural Nasal Decongestant Adult Daytime Cold Formula"; and
- "Natural Nasal Decongestant Adult Nighttime Cold Formula"
These four products' claims include "for the temporary relief of nasal congestion due to the common cold... soothe an irritated throat...cold formula."

Based on the above claims, these products are drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Natural Bronchial Syrup for Children and Natural Bronchial Syrup for Adults are labeled as dietary supplements. In

letters dated August 3, 2001 and March 13, 2002, our Center for Food Safety and Applied Nutrition (CFSAN) informed you that these products are not dietary supplements, and are drugs. Based on their intended uses as cough/cold preparations, these products are subject to the Over-the-Counter (OTC) monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (21 CFR 341).

The labeling for "Natural Nasal Decongestant Children's Nighttime Cold Formula" and "Natural Nasal Decongestant Children's Daytime Cold Formula," states that each product contains pseudoephedrine hydrochloride 15 mg/teaspoon. The dosing instructions on both products state "children take 1-2 teaspoonsful every 6 hours. Do not give to children under age 2." Following these instructions would produce a dosage range of 15 mg to 30 mg given every 6 hours to children ages two and above. Regulation 21 CFR 341.80(d)(1)(ii) for pseudoephedrine hydrochloride dosing states "Adults and children 12 years of age and over: 60 mg every 4 to 6 hours not to exceed 240 mg in 24 hours. Children 6 to under 12 years of age: 30 mg every 4 to 6 hours not to exceed 120 mg in 24 hours. Children 2 to under 6 years of age: 15 mg every 4 to 6 hours, not to exceed 60 mg in 24 hours. Children under 2: consult a doctor."

Moreover, by following your labeling dosing instructions, children ages two to under six would be given twice the amount of pseudoephedrine hydrochloride directed in the regulation. Based on the dosing instructions, these products present a health hazard to children, with the potential to cause temporary or medically reversible adverse health consequences in the two to under six age group.

The dosing instructions on the labeling for your product "Natural Nasal Decongestant Adult Daytime Cold Formula" and "Natural Nasal Decongestant Adult Nighttime Cold Formula" direct that "adults take 1-2 teaspoonsful every 6 hours. Children ages 6-12 take ½ - 1 teaspoonful every 6 hours. Do not give to children under age 2." The pseudoephedrine hydrochloride concentration for these products is 30 mg per teaspoon. These labeling directions for use violate the above-referenced monograph concerning adult and children dosing for each of your products. By following your labeling dosing instructions, adults and children 12 years of age and over would receive 30 mg if they use your directions of "1 teaspoonful." This would be half of the dose specified in the monograph for adults and children 12 years of age and over and it would result in an ineffective dose. These directions also violate the monograph concerning children's dosing. By following the labeling dosing directions, if children in the six to under twelve years age range take one-half teaspoonful, they would receive half of the children's dose for that age range, resulting in an ineffective dose. In addition, the product labeling omits appropriate dosing instructions for children ages two to under six years of age. The above-referenced monograph states "children 2 to under 6 years of age: 15 mg every 4 to 6 hours."

Furthermore, the above-referenced monograph [21 CFR 341.80(d)(1)(ii)] also requires labeling to include the maximum daily dosage of pseudoephedrine hydrochloride for all age groups. The labeling for your four "Natural Nasal Decongestant" products does not

provide these daily maximum dosages.

In addition, your products "Natural Bronchial Syrup" and "Natural Bronchial Syrup for Children" do not meet the requirements of 21 CFR 341.18, in that they do not contain guaifenesin, the only safe and effective active ingredient for use as an expectorant.

We are unaware of any evidence that establishes that the products discussed in this letter are generally recognized as safe and effective for their intended uses. Therefore, these products are "new drugs" as described in section 201(p) of the FDCA. They may not be legally marketed in the United States since no New Drug Applications (NDAs) have been approved for these products, as required by section 505 of the Act.

Furthermore, the products discussed in this letter are misbranded within the meaning of 502(f)(1) of the FDCA because their labeling fails to bear adequate directions for use for the conditions for which they are offered.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

It is important to note that all drug products that are subject to a final monograph must comply with the Drug Facts labeling format requirements of 21 CFR 201.66. We have attached a copy of the implementation dates as outlined in the Federal Register Notice of June 20, 2000, page 38193.

We also note that some of your labels give undue prominence to "other ingredients" (inactive ingredients). It is misleading to feature an inactive ingredient in a manner that creates an impression of therapeutic value greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). Examples found with your products include:

- "Natural Nasal Decongestant" adult and children formulas prominently display "echinacea" under the product name, implying it is an active ingredient. The only active ingredient listed on the product label is pseudoephedrine hydrochloride; and
- "Natural Nasal Decongestant Nighttime" adult and children formulas also prominently display "valerian" and "echinacea" under the product name implying they are active ingredients when only pseudoephedrine is listed as active ingredient.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur.

We request your response to the following questions:

1. An estimate of the quantities of the drugs manufactured or received within the past twelve (12) months;
2. An estimate of the size and frequency of shipments made in the past twelve (12) months;
3. An estimate of the amount of the drugs that are in inventory under your control and your estimate of the amount in distribution channels outside your control;
4. The date of discontinuance in the event you have already stopped marketing these drug products; and
5. Your intentions with respect to the disposition of your inventories and outstanding stocks in trade channels.

Please send your reply to Mark Lookabaugh, Compliance Officer, Food and Drug Administration, New England District Office, One Montvale Avenue, 4th Floor, Stoneham MA 02180. If you have any questions concerning this matter, please call Mr. Lookabaugh at (781) 596-7751.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello". The signature is stylized and includes a small flourish at the end.

Gail T. Costello
Director
New England District

Enclosure