

February 23, 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

**RE: Notification of a structure/function statement on dietary supplement product
LAXIT, marketed by TOMIL HERB INC.**

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. § 343(r)(6), notification is submitted for a structure/function statement appearing on the label and/or in labeling of the dietary supplement product LAXIT.

NAME / ADDRESS OF DISTRIBUTOR	TOMIL HERB INC 291 St. Lawrence Dr., Welland ON L3C 7H7, Canada
STATEMENT	Helps relieve occasional constipation, indigestion and digestive complaints.*
DISCLAIMER	*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.
DIETARY INGREDIENTS	Dandelion (stem) Flax (seed) Calendula (flower and leaf) Peppermint (stem) Damask Rose (flower) Plantain (leaf) Bitter Orange (peel) Senna (leaf) Alfalfa (stem) Frangula (bark)
DIETARY SUPPLEMENT PRODUCT NAME	LAXIT

Note: The following statement is included in the directions for use: "Only for occasional irregularity or occasional constipation."

The undersigned certifies that the information contained in this notice is complete and accurate, and that TOMIL HERB INC has substantiation that the statement made is truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions or need any additional information, please contact the undersigned at (289)-241-3629.

Sincerely,


George Manolov
Director of Marketing
TOMIL HERB INC



Enclosures
Certified Mail – Return Receipt Requested

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