

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 NEURELAXINE, marketed by TOMIL HERB INC.**

MAR 14 2005

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 NEURELAXINE.

<b>NAME / ADDRESS OF DISTRIBUTOR</b>	TOMIL HERB INC 291 St. Lawrence Dr., Welland ON L3C 7H7, Canada
<b>STATEMENT</b>	Helps calm the mind, support rest, and relieve nervous irritation and gastrointestinal disturbances.*
<b>DISCLAIMER</b>	<b>*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.</b>
<b>DIETARY INGREDIENTS</b>	Hops (cone) Rosemary (leaf and stem) Bladderwrack (whole plant) English Lavender (flower) Peppermint (leaf) Speedwell (stem) European Vervain (stem) Hawthorn (flower and leaf) Lemon Balm (leaf) Valerian (root)
<b>DIETARY SUPPLEMENT PRODUCT NAME</b>	NEURELAXINE

Note: The following statement is included in the directions for use: "For occasional sleeplessness only."

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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