

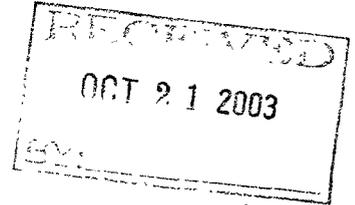
# NUMARK

LABORATORIES, INC.

164 NORTHFIELD AVENUE  
EDISON, NJ 08837  
800-338-8079 • FAX 732-225-0066

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October 8, 2003



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

Gentlemen:

This notification is being filed with your office in compliance with the requirements of 21CFR 101.93 to inform you of certain structure/function claims being added to the labeling of our product LIPO-FLAVONOID.

The name and address of the distributor of the product is:

NUMARK Laboratories  
164 Northfield Avenue  
Edison, NJ 08818

Three statements are being added to the product labeling as follows:

Statement 1

“Vitamins for ear health”

This statement is based on the fact that LIPO-FLAVONOID contains B-complex vitamins and vitamin C which have been demonstrated in the scientific literature to play a role in ear health.

Statement 2

“Improves circulation in the inner ear”

This statement is based on scientific literature which connects eridictyol glycoside, an ingredient in LIPO-FLAVONOID, with improvement of impaired circulation in the inner ear.

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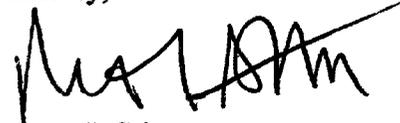
Statement 3

**“LIPO-FLAVONOID provides nutritional support to improve circulation in the inner ear”**

This statement represents a combination of Statement 1 and 2 and is based on the same scientific literature cited above.

I certify that the information contained in this notice is complete and accurate, and that NUMARK Laboratories has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. C. Stites', written over a horizontal line.

Robert C. Stites  
Chairman  
NUMARK Laboratories