

JUL 15 1999  
2707 '99 JUL 19 P3:18

Mr. James P. Farrell  
President  
Metabolic Technologies, Inc.  
Northwestern University/Evanston Research Park  
1840 Oak Avenue  
Evanston, Illinois 60201

Dear Mr. Farrell:

This is in response to your letter of July 6, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Metabolic Technologies, Inc. is making the following claim for the product **Metacalm-S**:

“Nutritional Support for Quitting Smoking”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claim that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely addiction to nicotine (i.e., smoking). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 285

Page 2 - Mr. James P. Farrell

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-MW140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:7/15/99:docname:66075.adv:disc38

**Metabolic**  
Technologies ▲ Incorporated

July 6, 1999



66075

Office of Special Nutritionals  
HFS-450  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

Dear Sirs:

Metabolic technologies, Inc., Northwestern University/Evanston Research Park, 1840 Oak Avenue, Evanston, IL 60201, is pleased to provide notification that the following statement:

• “Nutritional Support for Quitting Smoking”

has been a part of the labeling of the company’s product, Metacalm-S, since February 15, 1999.

Metabolic Technologies, Inc., has substantiation that this statement is truthful and not misleading.

The information contained in this notice is complete and accurate.

Sincerely,

A handwritten signature in cursive script that reads "James P. Farrell".

James P. Farrell  
President