



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 26 1999

0712 '99 SEP -3 110:39

Mr. James A. Taylor
Vice President of Marketing
The Dannon Company, Inc.
120 White Plains Road
Tarrytown, New York 10591-5536

Dear Mr. Taylor:

This is in response to your letter of August 11, 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 letter states that The Dannon Company, Inc., is making certain statements for a product you assert is a dietary supplement, namely, Actimel®.

We have reviewed your submission and information on the internet web site of your company (see www.danonegroup.com) for this product and have concluded that it, while purported to be a dietary supplement, is the subject of representations that establish the intent of this product to do something other than supplement the diet. The internet information for Actimel® represent this product as a conventional food through statements such as "It's an innovative breakfast drink," "...Actimel®, a breakfast drink featuring three active yogurt cultures," "New Actimel® Danone's delicious fermented milk drink," "wholesome 'fast food,' that goes anywhere, anytime," "...proved to kids - and their mothers - that snacks...," and "...as part of a balanced breakfast." Despite the nominal apparent use of the words "dietary supplement" in the statement of identity, the clear implication of the promotional information for this product is to represent Actimel® as a beverage, which is a conventional food.

The Act, as amended by the Dietary Supplement Health & Education Act of 1994, defines the term "dietary supplement" to exclude products represented for use as conventional foods and distinguishes dietary supplements from conventional foods in many important ways, e.g., different requirements with respect to safety, to the types of claims that can be made, and to the kind of information that must be provided in the nutrition label. Given the representations made for this product, as cited above, the product is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and cannot continue to be marketed as a dietary supplement.

Under the Federal Food, Drug, and Cosmetic Act, any ingredient intentionally added to a conventional food like beverages must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. FDA would expect that the ingredients contained in

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LET 296

Page 2 - Mr. James A. Taylor

Actimel® are approved food additives or GRAS for use in conventional food. We are also concerned about the statements you are making on the labels and in the labeling of your product, particularly the claims regarding the effect on the immune system. If you intend to market this product as a food bearing claims of these kind, such claims must be in the form of an appropriate claim to affect the structure or function of the body and the claimed effect must be achieved through nutritive value. While this product can no longer be marketed as a dietary supplement, the product may be marketed as a conventional food provided that the ingredients in this food meet the safety requirements of the Act, the product is properly labeled with a Nutrition Facts panel, and any claims to affect the structure or function of the body are achieved through nutritive value.

Please advise us as soon as possible whether you intend to continue to market this product and if so, how you intend to bring it into compliance, including your basis for concluding that the ingredients and claims meet the safety and labeling requirements of the Act.

Please contact us if we may be of 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

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, New York District Office, Office of Compliance, HFR-NE140

Page 3 - Mr. James A. Taylor

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-1

HFS-3

HFS-4

HFS-22 (CCO)

HFS-150 (Wilkening, Foret, Kelker)

HFS-206 (GPauli)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey, Nickerson, Dorsey)

HFV-228 (SBenz)

r/d:HFS-456:RMoore:8/17/99

revised per HFS-455:LLarsen:8/18/99

f/t:HFS-456:rjm:8/18/99:docname:66586.adv:disc39

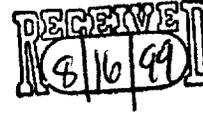


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The Dannon Company, Inc.

120 White Plains Road • Tarrytown, NY 10591-5536 • Phone (914) 366-9700

JAMES A. TAYLOR
VICE PRESIDENT OF MARKETING



August 11, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, N.W.
Washington, DC 20204

CERTIFIED RETURN RECEIPT

Dear Sir / Madam:

Notice is hereby provided under Section 403(r)(6) of the Federal Food Drug and Cosmetic Act, and 21 CFR 101.93, of the use of a structure / function statement on a new dietary supplement manufactured and distributed by the Dannon Company, Inc.

Name and Address of the manufacturer of the dietary supplement that bears the statement	The Dannon Company, Inc. 120 White Plains Road Tarrytown, NY 10591-5536
Text of the statements being made on label and in labeling	Actimek® helps strengthen your natural defenses. Actimek® helps fortify your natural defenses. Actimek® primes the immune system. Actimek® helps to keep your immune system alert.
The name of the dietary supplement	Actimek® (Dietary supplement containing <i>Lactobacillus casei</i>)

I hereby certify the accuracy of the information presented and contained in this notification.

I hereby certify that the information hereby provided is complete and accurate and that The Dannon Company, Inc. has substantiation that the statements made on label and in labeling are truthful and not misleading.

Sincerely,

James A. Taylor
Vice President of Marketing