

JUN 21 1999

2706 '99 JUL 19 P3:18

Myron Cooper  
Vice President-Technical Services  
Hain Food Group  
255 West Carob Street  
Compton, California 90220

Dear Mr. Cooper:

This is in response to your letter of September 25, 1998 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)) and the October 23, 1998 letter on your behalf from Mr. Anthony L. Young, Piper & Marbury L.L.P., acting as counsel for the Hain Food Group, Inc. Your letter states that the Hain Food Group, Inc., is making certain statements for 4 products you assert are dietary supplements. The products are Kitchen Prescription<sup>TM</sup> Herbal Supplement Chunky Tomato with St. John's Wort, Kitchen Prescription<sup>TM</sup> Creamy Split Pea with St. John's Wort, Kitchen Prescription<sup>TM</sup> Country Vegetable with Echinacea, and Kitchen Prescription<sup>TM</sup> Chicken Broth and Noodles with Echinacea.

We have reviewed the labels for these foods and have concluded that the soups, while labeled as herbal supplements, bear label representations that establish the intent of these products to do something other than supplement the diet. The labels for the Kitchen Prescription<sup>TM</sup> line represent these products as conventional foods through statements such as "A soothing cup of soup," "...familiar, comfortable, and convenient can of soup," "HEAT'N SERVE," "We've cooked up ripe, red tomatoes with tasty seasonings, then blended our soup...", "We've cooked up tender split peas with tasty seasonings, then blended our soup...", "We've cooked up hearty vegetables with tasty seasonings, then blended our soup...", "We've cooked up rich chicken broth with tender noodles and tasty seasonings including ginger, then blended our soup..," and through the identity statements that use, in part, names commonly associated with soups, for example, "chunky tomato," "creamy split pea," "country vegetable," and "chicken broth and noodles," and vignettes that picture the products in a common soup use. Despite the nominal use of the words "herbal supplement" in the statement of identity, the clear implication of the label as a whole is to represent the Kitchen Prescription<sup>TM</sup> products as conventional foods.

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. Therefore, these products are not dietary supplements within the meaning of 21 U.S.C. 321(ff) and cannot continue to be marketed as dietary supplements.

975-0163

LET 284

Under the Federal Food, Drug, and Cosmetic Act, any ingredient intentionally added to a conventional food like soup 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 approved causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. Although a hypericin-free alcohol distillate of St. John's Wort leaves, flowers, and caulis is listed in a food additive regulation, the food additive regulation limits the use to flavoring in alcoholic beverages. Other than the food additive regulation listing St. John's Wort for use in alcoholic beverages, we are not aware of a basis for concluding that St. John's Wort is GRAS for general use in conventional food. Similarly, we are not aware of a basis for concluding echinacea is GRAS for use in conventional food.

We are also concerned about several other statements on the labels of your products, particularly the claims regarding the effect on the immune system and the effect on mood. If you intend to market these products as 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.

We are also concerned about the name of the line of products, Kitchen Prescription™. The use of the term "prescription" suggests that the intended use of the product is to do something other than supplement the diet. The use of the term "prescription" suggests the product may be intended to diagnose, cure, mitigate, treat, or prevent a disease. Under the Act, the use of this type of term is inappropriate for a food product. If you wish to market your products as foods, the name of the line of products would need to be changed.

While these products can no longer be marketed as dietary supplements, the products may be marketed as conventional foods provided that the ingredients in these foods meet the safety requirements of the Act, the products are properly labeled with a Nutrition Facts panel instead of a Supplement Facts panel, the label does not suggest that the products have an effect on disease, 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 these

Page -3      Mr. Myron Cooper

products and if so, how you intend to bring them into compliance, including your basis for concluding that the ingredients and claims meet the safety and labeling requirements of the Act.

Sincerely yours,

John B. Foret  
Director  
Division of Programs  
and Enforcement Policy  
Office of Food Labeling  
Center for Food Safety  
and Applied Nutrition

cc:

Anthony L. Young  
Piper & Marbury  
1200 Nineteenth Street, N.W.  
Washington, D.C. 20036

cc:

GCF-1 (Barnett, Nickerson)  
HF-11 (Shuren)  
HF-13 (Witt)  
HFS-1 (Levitt)  
HFS-4 (Lake)  
HFS-450 (Yetley)  
HFS-452 (Lewis)  
HFS-455 (Larsen)  
HFS-456 (Moore)  
HFS-150 (Falci)  
HFS-151 (McCowin)  
HFS-155 (Foret)  
HFS-156 (Kelker, Kraus, e/f, r/f, subject)  
r/d:HFS-156:JSKraus:10/19/98  
revised:HFS-156:JSKraus 10/30/98, 3/3/99, 4/9/99  
HFS- 205:GPauli:4/9/99  
HFS-456:RJMoore:4/13/99  
HFS-156:JSKraus per JBForet 4/15/99  
GCF-1:Alexa Barnett:5/6/99  
HFS-155:JBForet:5/13/99  
HFS-156:JSKraus per WKelker per JLevitt:6/15/99  
F/t:sls:6/18/99:205-4122 Doc. Hain

# THE HAIN FOOD GROUP

255 West Carob Street  
Compton, California 90220  
Phone: (310) 886-8200 x118  
Fax: (310) 886-8219

61428

September 25, 1998

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

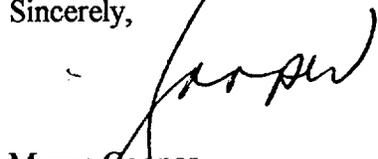
RECEIVED  
9/28/98

This is a notification pursuant to 21 U.S.C. @ 343 (a) (6) that The Hain Food Group, Inc., Uniondale, New York 11553, is making the following statements:

- (1) "Give your mood a natural lift" for a dietary supplement containing St. John's Wort. The product names are:
  - Kitchen Prescription Herbal Supplement Chunky Tomato with St. John's Wort
  - Kitchen Prescription Creamy Split Pea with St. John's Wort
  
- (2) "Support your immune system" for a dietary supplement containing Echinacea. The product names are:
  - Kitchen Prescription Country Vegetable with Echinacea
  - Kitchen Prescription Chicken Broth and Noodles with Echinacea

The information contained herein is accurate and The Hain Food Group, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,



Myron Cooper  
Vice President - Technical Services

- cc: Irwin Simon - Uniondale  
Andrew Jacobson - Uniondale  
Leslie Hyde - Compton  
Cathy Hwang - Compton  
Susan Menell - Compton  
Maureen Putman - Uniondale  
Paul Fallaw - Uniondale  
Anthony L. Young - Piper & Marbury

