



MAR 13 1998

Rec'd 3/20/98

Mr. Mike Gross
Quality Assurance Manager
Celestial Seasonings, Inc.
4600 Sleepytime Drive
Boulder, Colorado 80301-3292

Dear Mr. Gross:

This is in response to your letters of February 3, 1997 and January 8, 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)). Your submission states that Celestial Seasonings, Inc. is making the following claims, among others, for the products:

Celestial Herbal Extracts Echinacea Cold Care

"We all know there's no cure for the common cold. But one caplet of Echinacea Cold Care daily during cold and flu season can boost your defenses"

Celestial Seasonings Echinacea Standardized Herbal Extracts

"Take Echinacea as needed during cold season"
"For Cold Season"
"Take Echinacea as needed during cold season"

Celestial Seasonings Echinacea Cold Season Standardized Herbal Extracts

"Echinacea helps the body maintain its natural defenses--especially useful during cold season"
"Echinacea Cold Season is expertly blended to give you just the right amount and potency of herbs and nutrients you need for supporting your body's defenses"
"Echinacea Cold Season is a comprehensive blend that naturally supports your body's defenses"
"This unique formula contains just the right blend of ingredients you need during cold season"

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 statements that you are making for these

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products and, in the case of "Celestial herbal Extracts Echinacea Cold Care" and "Celestial Seasonings Echinacea Cold Season Standardized Herbal Extracts," the inclusion of the terms "cold care" and "cold season" in the product names, suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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 we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting 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, Denver District Office, Office of Compliance, HFR-SW340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/12/98
Init:GCF-1:LNickerson:3/12/98
f/t:HFS-456:rjm:3/12/98:docname:56673.adv:disc26



CELESTIAL SEASONINGS, INC.

4600 Sleepytime Drive, Boulder, CO 80301-3292 USA (303) 530-5300

February 3, 1997

Office of Special Nutritionals
HFS 450
200 C Street SW
Washington, DC 20204

As per Section 6 of the Dietary Supplement Health and Education Act of 1994, I respectfully submit the following information:

Name and address:

Celestial Seasonings, Inc.
4601 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- We all know there's no cure for the common cold. But one caplet of Echinacea Cold Care daily during cold and flu season can boost your defenses.
- We guarantee the exact, standardized amount of ingredients you see on the label in EVERY dosage for an effective, consistent and safe way to boost the body's defenses.

Name of the Dietary Ingredient(s):

Echinacea extract, Vitamin C, Zinc,

Name of the dietary supplement (including brand name):

Celestial Herbal Extracts™
Echinacea Cold Care

I hereby certify that the information contained in the above notice is complete and accurate, and that Celestial Seasonings, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Mike Gross
Quality Assurance Manager



CELESTIAL SEASONINGS, INC.

4600 Sleepytime Drive, Boulder, CO 80301-3292 USA (303) 530-5300

January 8, 1998

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Office of Special Nutritionals
HFS 450
200 C Street SW
Washington, DC 20204

As per Section 6 of the Dietary Supplement Health and Education Act of 1994, I respectfully submit the following information:

Name and address:

Celestial Seasonings, Inc.
4600 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- A natural alternative for maintaining good health.
- Echinacea helps support the body's defenses.
- Take Echinacea as needed during cold season.
- For Cold Season.
- Celestial Seasonings Echinacea standardized herbal extract is a natural way to maintain your good health.
- Take Echinacea as needed during cold season.

Ingredient statement:

Echinacea Extract

Name of the dietary supplement (including brand name):

Celestial Seasonings™
Echinacea Standardized Herbal Extracts

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

Sincerely,

Mike Gross
Technical Services Manager

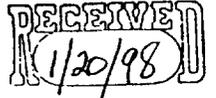
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CELESTIAL SEASONINGS, INC.

4600 Sleepytime Drive, Boulder, CO 80301-3292 USA (303) 530-5300

January 8, 1998



Office of Special Nutritionals
HFS 450
200 C Street SW
Washington, DC 20204

As per Section 6 of the Dietary Supplement Health and Education Act of 1994, I respectfully submit the following information:

Name and address:

Celestial Seasonings, Inc.
4600 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- Comprehensive formula to support the body's defenses.
- Echinacea helps the body maintain its natural defenses -- especially useful during cold season.
- Vitamin C & zinc are essential nutrients for support of the defense system.
- Echinacea Cold Season is expertly blended to give you just the right amount and potency of herbs and nutrients you need for supporting your body's defenses.
- Echinacea Cold Season is a comprehensive blend that naturally supports your body's defenses.
- This unique formula contains just the right blend of ingredients you need during cold season.

Ingredient statement:

Vitamin C, zinc, Echinacea root extract.

Name of the dietary supplement (including brand name):

Celestial Seasonings™
Echinacea Cold Season Standardized Herbal Extracts

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

Sincerely,

Mike Gross
Technical Services Manager

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