



MAR 13 1998

Rec'd 3/26/98

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

Dear Mr. Gross:

This is in response to your letters of October 29, 1996 and February 3, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Botalia Pharmaceutical, Inc. is making the following statements, among others, for the products:

Herbal Choice Echinacea Extract

"Herbal Choice Standardized Echinacea extract enhances the body's natural defenses to help you feel your best during cold and flu season"
"For cold and flu season"

Botalia Gold Echinacea Extract

"Cold & Flu Season"

Botalia Gold Echinacea Extract

"Echinacea boosts the body's natural defense system and can be especially helpful during cold and flu season"
"For Cold & Flu 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 products suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. 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.

975-0163

LET 134

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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:botalia.adv:disc26

botalia

PHARMACEUTICAL, INC.

October 29, 1996

Office of Special Nutritionals
HFS 450
200 C Street SW
Washington D.C. 20204

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

Name and address:

Botalia Pharmaceutical Inc.
4600 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- Botalia Gold Standardized Echinacea Extract stimulates the immune system to increase the body's resistance.
- For the immune system
- Cold & Flu Season

Name of the Dietary Ingredient(s):

Echinacea, *Echinacea angustifolia*

Name of the dietary supplement (including brand name):

Botalia Gold™
Echinacea Extract

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



Mike Gross
Quality Assurance Manager

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11/17/98

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PHARMACEUTICAL, INC.

October 29, 1996

Office of Special Nutritionals
HFS 450
200 C Street SW
Washington D.C. 20204

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

Name and address:

Botalia Pharmaceutical Inc.
4600 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- Our level of standardization is the ideal level for providing effective, maximum support to help maintain your body's natural defenses.
- Herbal Choice Standardized Echinacea extract enhances the body's natural defenses to help you feel your best during cold and flu season.
- For cold and flu season

Name of the Dietary Ingredient(s):

Echinacea, *Echinacea angustifolia*

Name of the dietary supplement (including brand name):

Herbal Choice™
Echinacea Extract

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



Mike Gross
Quality Assurance Manager

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:

Botalia Pharmaceutical Inc.
4600 Sleepytime Drive
Boulder, CO 80301-3292

Text of statement(s):

- Our level of standardization is the ideal for boosting the body's natural defenses.
- For Cold & Flu Season
- Echinacea boosts the body's natural defense system and can be especially helpful during cold and flu season.

Name of the Dietary Ingredient(s):

Echinacea, *Echinacea angustifolia and purpurea*

Name of the dietary supplement (including brand name):

Botalia Gold™
Echinacea Extract

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

Sincerely,



Mike Gross
Quality Assurance Manager