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Mike Gross
Quality Assurance Manager
Botalia Pharmaceutical, Inc.
4600 Sleepytime Drive
Boulder, Colorado 80301-3292

Dear Mr. Gross:

This is in response to your letter of February 3, 1997 making a submission 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 you are making the following statements on the label or in the labeling of your product "Botalia Gold™ Feverfew Extract:"

Our level of standardization is the ideal level for helping to prevent headache and migraine pain.

For Headaches

Feverfew may help prevent headaches and migraines by regulating healthy levels of noradrenalin, acetylcholine, prostaglandins, histamine, and serotonin.

Section 403(r)(6) of the Act makes it 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 statement that you are making for this product suggests that it is intended to prevent or treat a disease, namely, headache and migraine pain. This claim does not meet the requirements of section 403(r)(6) of the Act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act, and that it is subject to regulation under the

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drug provisions of the Act. If you intend to make a claim 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 yours,

James 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, Denver District Office, (Office of Compliance), HFR-SW200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

cc:

HFA-224 (w/incoming)
HFS-22 (CCO, KCarson)
HFS-450 (w/control slip OSN#51074, r/f)
HFS-456 (Latham, Moore w/cpy incoming)
HFD-304 (Aronson)
HFS-600 (Reynolds)
r/d:HFS-456:JELatham;jel:03/18/97:DocName#51074.OSN:Disc3
Initial:R.Moore:03/20/97

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 level for helping to prevent headache and migraine pain.
- For Headaches
- Feverfew may help prevent headaches and migraines by regulating healthy levels of noradrenalin, acetylcholine, prostaglandins, histamine, and serotonin.

Name of the Dietary Ingredient(s):

Feverfew, *Tanacetum parthenium*

Name of the dietary supplement (including brand name):

Botalia Gold™
Feverfew 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