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AUG 31 2006

Vincent J. Gilday  
Chief Operating Officer  
Blaine Pharmaceuticals  
1717 Dixie Highway  
Suite 700  
Fort Wright, Kentucky 41011

Dear Mr. Gilday:

This is in response to your letters to the Food and Drug Administration (FDA) dated July 26, 2006 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In your letters, you state that the following statements are being made for the following products:

DiaSense™ Multivitamin

“[M]anage the impact of diabetes.”

“[I]mprove the health and well-being of those living with, or at risk for, diabetes.”

“Formulated especially for those with diabetes and pre-diabetes.”

“[M]anage the impact of diabetes on your health.”

DiaSense™ Magnesium

“[M]anage the impact of diabetes.”

“[I]mprove the health and well-being of those living with, or at risk for, diabetes.”

“[A]lleviate day-to-day symptoms, such as leg cramps and migraines.”

“[M]anage the impact of diabetes on your health.”

DiaSense™ Chromium

“[M]anage the impact of diabetes on your health.”

“[H]elp balance glucose levels.”

“If you have high blood glucose, chromium may help.”

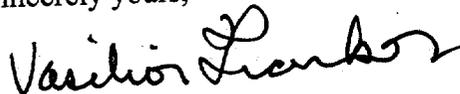
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. 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

Page 2 - Mr. Vincent J. Gilday

claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Cincinnati District Office, Office of Compliance, HFR-CE640



1717 Dixie Highway, Suite 700 • Fort Wright, KY 41011 • www.blainepharma.com  
859.344.9600 phone • 800.633.9353 toll free • 859.344.9601 fax

July 26, 2006

Via Federal Express

Office of Nutritional Products, Labeling,  
and Dietary Supplements (HFS 800)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street S.W.  
Washington, D.C. 20204

JUL 31 2006

Re: Dietary Supplement Notification for Blaine Pharmaceuticals

Dear Sir or Madam:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) that Blaine Pharmaceuticals is offering for sale DiaSense™ Multivitamin as a dietary supplement. It contains the following structure/function statements:

**Statements:**

“Enhances nutrition and metabolism”

“It makes good sense to manage the impact of diabetes. Let DiaSense™ Multivitamin help, as part of a family of products specifically formulated to improve the health and well-being of those living with, or at risk for, diabetes.”

“DiaSense™ Multivitamin has the nutrients needed to support glucose balance in healthy individuals”

“DiaSense™ Multivitamin has the nutrients needed to help protect from free radical damage”

“DiaSense™ Multivitamin has the nutrients needed to promote nerve function and eye health”

“Just one tablet provides the key nutrients your body needs every day.”

“If you have diabetes, DiaSense™ Multivitamin can provide the key nutrients you may be lacking”

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“Formulated especially for those with diabetes and pre-diabetes”

“Provides needed dosage of vitamins, minerals, and antioxidants in just one tablet”

“Safe to take in combination with other DiaSense™ products as you manage the impact of diabetes on your health.”

**Subject of Claims:** Multivitamin, Mineral and Antioxidant formulation including: Vitamin A, Vitamin C, Vitamin D, Vitamin E, Thiamine (B-1), Riboflavin (B-2), Niacin, Vitamin B-6, Folic Acid, Vitamin B-12, Biotin, Pantothenic Acid, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Potassium, Alpha Lipoic Acid, Coenzyme Q-10, Lutein, Vanadium

**Name of Supplement:** DiaSense™ Multivitamin

The information contained in this notice is complete and accurate and the packaging contains the proper disclaimer. The files of Blaine Pharmaceuticals contain substantiation that the statements made are truthful and not misleading.

Thank you for your kind attention to this matter. Should you have any questions pertaining to this notification, please contact me at (859) 344-9600 – Ext. 20.

Sincerely,



Vincent J. Gilday  
Chief Operating Officer



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and Dietary Supplements (HFS 800)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street S.W.  
Washington, D.C. 20204

JUL 31 2006

Re: Dietary Supplement Notification for Blaine Pharmaceuticals

Dear Sir or Madam:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Blaine Pharmaceuticals is offering for sale DiaSense™ Magnesium (from Magnesium Oxide) as a dietary supplement. It contains the following structure/function statements:

**Statements:**

“Promotes good heart health”

“It makes good sense to manage the impact of diabetes. Let DiaSense™ Magnesium help, as part of a family of products specifically formulated to improve the health and well-being of those living with, or at risk for, diabetes.”

“Studies show magnesium can enhance long-term cardiovascular health”

“Studies show magnesium can alleviate day-to-day symptoms, such as leg cramps and migraines”

“Just two tablets provide the magnesium your body needs every day.”

“If you have high blood glucose, chances are you need magnesium.”

“DiaSense™ Magnesium for maximum effectiveness”

“Provides needed dosage in just two easy-to-swallow tablets”

“Safe to take in combination with other DiaSense™ products as you manage the impact of diabetes on your health.”

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**Subject of Claims:** Magnesium Oxide

**Name of Supplement:** DiaSense™ Magnesium

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Thank you for your kind attention to this matter. Should you have any questions pertaining to this notification, please contact me at (859) 344-9600 – Ext. 20.

Sincerely,



Vincent J. Gilday, Jr.  
Chief Operating Officer



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and Dietary Supplements (HFS 800)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street S.W.  
Washington, D.C. 20204

JUL 31 2006

Re: Dietary Supplement Notification for Blaine Pharmaceuticals

Dear Sir or Madam:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) that Blaine Pharmaceuticals is offering for sale DiaSense™ Chromium (from chromium polynicotinate) as a dietary supplement. It contains the following structure/function statements:

**Statements:**

- “Supports glucose balance”
- “Studies show chromium can help balance glucose levels”
- “Studies show chromium can aid in carbohydrate metabolism”
- “Studies show chromium can play a role in healthy body weight”
- “If you have high blood glucose, chromium may help.”
- “DiaSense Chromium for safety and effectiveness”
- “Safe to take in combination with other DiaSense products as you manage the impact of diabetes on your health.”

**Subject of Claims:** Chromium as Chromium Polynicotinate (ChromeMate®)

**Name of Supplement:** DiaSense™ Chromium

The information contained in this notice is complete and accurate and the packaging contains the proper disclaimer. The files of Blaine Pharmaceuticals contain substantiation that the statements made are truthful and not misleading.

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Page 2

Thank you for your kind attention to this matter. Should you have any questions pertaining to this notification, please contact me at (859) 344-9600 – Ext. 20.

Sincerely,

A handwritten signature in cursive script that reads "Vincent J. Gilday, Jr." with a horizontal line extending to the right.

Vincent J. Gilday, Jr.  
Chief Operating Officer