Metagenics 8/13/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021
Telephone: 425-302-0340
FAX: 425-302-0402

August 13, 2013

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 13-27

John P. Troup, Ph.D., Chief Science Officer
Metagenics, Inc.
P.O. Box 1729
Gig Harbor, Washington 98335

WARNING LETTER

Dear Dr. Troup:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the internet address www.metagenics.com in August 2013, and has determined that you take orders there for the products UltraClear®, UltraClear® Plus, UltraClear® Plus pH, UltraClear RENEW™, GI Sustain, UltraMeal® Plus, UltraMeal® Plus 360, UltraInflamX®, UltraInflamX® Plus 360, UltraGlycemX®, GlycemX™ 360, Ultracare for Kids®, BariatrX Essentials Bariatric Meal, and ArginCor. These products are labeled as “medical foods,” and the labeling claims on your website represent these products as medical foods for the dietary management of a variety of medical conditions.

Based on our review, we have determined that these products are misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343(a)(1)], because the labeling is false and misleading in that the products are labeled and marketed as medical foods

but do not meet the statutory definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in 21 CFR 101.9(j)(8). Furthermore, because these products are labeled and marketed as medical foods, but do not meet the statutory definition of a medical food, FDA has determined that these products are promoted for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. You can find the Act and its implementing regulations on FDA's website at ***http://www.fda.gov (http://www.fda.gov/)***.

Misbranded Food

The Orphan Drug Act defines "medical food" as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The regulation in 21 CFR 101.9(j)(8) sets forth criteria to clarify the statutory definition of a medical food. Specifically, this regulation provides that a food is a medical food only if:

i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;
ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
iii. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
iv. It is intended to be used under medical supervision; and
v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

FDA considers the statutory definition of "medical food" to narrowly constrain the types of products that fit within this category.**[1]** In addition to other criteria, medical foods must be for the dietary management of a specific disorder, disease, or condition for which there are distinctive nutritional requirements and must be intended to be used under medical supervision.**[2]** Patients with such a disorder, disease, or condition must have a limited capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or have other special medically determined nutrient requirements, which cannot be managed by the modification of the normal diet alone.**[3]** Medical foods are not those simply recommended by a physician as part of an overall diet to reduce the risk of a disease or condition.**[4]**

As set forth in the statutory definition of a medical food, a medical food must be intended for the dietary management of a disease or condition for which there are distinctive nutritional requirements. Further, pursuant to 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. As discussed in more detail below, your products do not meet these

requirements and therefore do not qualify as medical foods under either the statute or FDA's regulations.

- **UltraClear**, **UltraClear Plus**, **UltraClear Plus pH**: Your labeling states that these products are intended for patients with chronic fatigue syndrome. FDA is not aware of any distinctive nutritional requirement for patients with chronic fatigue syndrome, nor is FDA aware of any evidence that patients with chronic fatigue syndrome have a limited or impaired capacity to ingest, digest, absorb, or metabolize any specific nutrients.
- **UltraClear RENEW**: Your labeling states that this product is intended for patients with fibromyalgia. FDA is not aware of any distinctive nutritional requirement for patients with fibromyalgia, nor is FDA aware of any evidence that patients with fibromyalgia have a limited or impaired capacity to ingest, digest, absorb, or metabolize any specific nutrients.
- **GI Sustain**: Your labeling states that this product is intended for patients with leaky gut syndrome. FDA is not aware of any distinctive nutritional requirement for patients with leaky gut syndrome, nor is FDA aware of any evidence that patients with leaky gut syndrome have a limited or impaired capacity to ingest, digest, absorb, or metabolize any specific nutrients.
- **UltraMeal Plus, UltraMeal Plus 360**: Your labeling states that these products are intended for patients with metabolic syndrome and cardiovascular disease. FDA is not aware of any distinctive nutritional requirement for patients with metabolic syndrome or cardiovascular disease that cannot be met through dietary modification alone.
- **UltraInflamX, UltraInflamX Plus 360**: Your labeling states that these products are intended for patients with inflammatory bowel conditions and/or inflammatory bowel disease. FDA is not aware of any distinctive nutritional requirement for patients with inflammatory bowel conditions or inflammatory bowel disease.
- **UltraGlycemX, GlycemX 360**: Your labeling states that these products are intended for patients with Type 2 Diabetes. FDA is not aware of any distinctive nutritional requirement or unique nutrient need for patients with Type 2 Diabetes that cannot be met through dietary modification alone.
- **Ultracare for Kids**: Your labeling states that this product is intended for patients with atopic disorders such as eczema, rhinitis, and allergy-responsive asthma. FDA is not aware of any distinctive nutritional requirement for patients with atopic disorders such as eczema, rhinitis, and allergy-responsive asthma.
- **BariatrX Essentials Bariatric Meal**: Your labeling states that this product is intended for bariatric patients pre- and post-operatively. FDA is not aware of any distinctive nutritional requirement for bariatric patients pre- and post-operatively that cannot be met through dietary modification alone, which may include use of a daily multi-vitamin.
- **ArginCor**: Your labeling states that this product is intended for patients with peripheral artery disease. FDA is not aware of any distinctive nutritional requirement for patients with peripheral artery disease.

Because these products are intended to support diseases or conditions that do not have distinct requirements for certain nutrients, these products do not meet the statutory definition or regulatory criterion for medical foods set forth in 21 CFR 101.9(j)(8)(ii). Accordingly, these products are misbranded within the meaning of Section 403(a)(1) of the Act because their labeling is false or

misleading in that the products are labeled as a medical food but do not meet the definition of a medical food.

Unapproved New Drug

Additionally, your UltraClear®, UltraClear® Plus, UltraClear® Plus pH, UltraClear RENEW™, GI Sustain, UltraMeal® Plus, UltraMeal® Plus 360, UltraInflamX®, UltraInflamX® Plus 360, UltraGlycemX®, GlycemX™ 360, Ultracare for Kids®, and ArginCor products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act. The therapeutic claims on your website establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Specific examples of claims on your website, www.metagenics.com that provides evidence that your products are intended for use as drugs are as follows:
UltraClear®

- “[A] medical food formulated to provide specialized nutritional support to address…liver detoxification function in patients with chronic fatigue syndrome...”

UltraClear Plus®

- “[A] medical food formulated to provide enhanced, specialized nutritional support for patients with chronic fatigue syndrome...”

UltraClear® Plus pH

- “[A] medical food formulated to provide enhanced, specialized nutritional support for patients with chronic fatigue syndrome...”

UltraClear RENEW™

- “[A] medical food formulated to provide specialized nutritional support to help address altered pain signaling and neuromuscular function in patients with fibromyalgia.”

GI Sustain

- “Leaky Gut Syndrome”
- “[A] medical food formulated to provide specialized nutritional support…for patients with leaky gut syndrome.”

UltraMeal® Plus

- “Nutritional Support for the Management of Conditions Associated with Metabolic Syndrome and Cardiovascular Disease”
- “[A] medical food formulated to nutritionally support the management of conditions associated with metabolic syndrome and cardiovascular diseases including hypercholesterolemia, hypertriglyceridemia, and hypertension.”

UltraMeal® Plus 360

- “Nutritional Support for the Management of Conditions Associated with Metabolic Syndrome and Cardiovascular Disease”
- “[A] medical food formulated to provide specialized, multi-mechanistic nutritional support for patients with metabolic syndrome and cardiovascular disease...”

UltraInflamX®

- “[A] medical food formulated to provide specialized nutritional support for patients with inflammatory bowel conditions, such as ulcerative colitis and Crohn’s disease.”

UltraInflamX Plus 360®

- “[A] medical food formulated to provide specialized nutritional support…for patients experiencing inflammation and pain associated with inflammatory bowel disease.”

UltraGlycemX®

- “Nutritional Support for Conditions Associated with Type 2 Diabetes”
- “[A] medical food formulated to meet the specialized nutritional needs of patients with type 2 diabetes, insulin resistance, and hypoglycemia…”

GlycemX 360™

- “Nutritional Support for Conditions Associated with Type 2 Diabetes”
- “[A] … medical food formulated to provide specialized nutritional support…for patients with type 2 diabetes.”

UltraCare for Kids®

- “High Quality Nutritional Support for Children with Atopic Disorders”
- “[S]pecifically formulated for children with atopic disorders such as eczema, rhinitis, and allergy-response asthma…support the reduction of symptoms associated with atopic disorders.”

ArginCor™

- “Medical Food for Peripheral Artery Disease”
- “[A] medical food formulated to provide specialized nutritional support for patients with peripheral artery disease.”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

This letter is not an all-inclusive list of violations in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its

implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for all of your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to implement lasting corrective action of these violations may result in regulatory action being initiated by FDA without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office in writing, within fifteen working days from your receipt of this letter, of the specific steps you have taken to correct the noted violations. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: LCDR Cynthia White, Compliance Officer, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact LCDR White at (425) 302-0422.

Sincerely,
/S/
Celeste M. Corcoran, Ph.D.
Acting District Director

cc: Commissioned Official
Washington State Department of Agriculture
Food Safety Program
P.O. Box 425620
Olympia, Washington 98504-2560

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[1] *See* 56 Fed. Reg. 60366, 60377 (Nov. 27, 1991); *see also* Guidance for Industry: Frequently Asked Questions About Medical Foods, May 2007.
[2] *See* 21 U.S.C. § 360ee(b)(3); *see also* 56 Fed. Reg. 60377.
[3] *See* 21 CFR 101.9(j)(8)(ii); *see also* 56 Fed. Reg. 60377.

[4] *See* 56 Fed. Reg. 60377.

More in 2013 (/ICECI/EnforcementActions/WarningLetters/2013/default.htm)