



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District 94337d

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
Return Receipt Requested

October 1, 2003

W/L 53-03

Jeffrey J. Katke, CEO
Metagenics, Inc.
100 Avenida La Pata
San Clemente, California 92673

Dear Mr. Katke:

Investigators from the U.S. Food and Drug Administration (FDA) performed an inspection of your facility from May 6, 2003, to May 19, 2003. During the inspection, the investigators collected labels from your products UltraClear[®], UltraMeal[®], UltraInflamX[™], and UltraGlycemX[™]. FDA reviewed the labels for these products and found that the labels cause the products to violate the Federal Food, Drug, and Cosmetic Act (the Act) in several respects.

The products are labeled as “medical foods,” and are represented on the labels as intended for use with a variety of medical conditions. The products do not meet the definition of a medical food in 21 USC 360ee(b)(3), which defines a 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 regulations further define a medical food as one that is intended for the dietary management of a patient who has special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the diet alone [21 CFR 101.9(j)(8)(ii)]. Your products UltraClear[®], UltraMeal[®], UltraInflamX[™], and UltraGlycemX[™] are not medical foods because the diseases and conditions described in the product labels do not have distinct nutritional requirements and because the products do not have any unique impact on the dietary management of those diseases and conditions beyond that which could be achieved by modification of the normal diet alone.

Because UltraClear[®], UltraMeal[®], UltraInflamX[™], and UltraGlycemX[™] do not meet the definition of a medical food, they are not subject to the exemption from nutrition labeling afforded medical foods. Therefore, your products are misbranded within the meaning of Section 403(q)(1) of the Act because the labels do not bear nutrition labeling in the appropriate format, as prescribed in 21 CFR 101.9.

In addition, your products bear label claims suggesting that they are useful in the treatment of various diseases. These claims include:

- “UltraClear[®] is formulated to nutritionally support overall liver detoxification activity and the removal of potentially harmful toxins associated with health conditions such as food allergies, chronic fatigue syndrome, ... and migraine headaches.
- “UltraMeal[®] is ... designed to nutritionally support the management of conditions associated with altered body composition, including ... hypertension ...”
- “UltraInflamX[™] NUTRITIONAL SUPPORT FOR INFLAMMATION” and “UltraInflamX[™] is designed to nutritionally support patients with chronic inflammatory conditions, such as osteoarthritis, rheumatoid arthritis, psoriasis and eczema, as well as other conditions associated with excessive inflammation.”
- “Designed to provide nutritional support for those with insulin resistance, or type 2 diabetes, UltraGlycemX[™] promotes a healthy insulin and glucose response.”

The presence of the above referenced claims indicates that the products are intended to treat, cure, or mitigate diseases. Such claims are evidence that the products are intended for use as drugs within the meaning of Section 201(g)(1)(B) of the Act. The products are new drugs under section 201(p) of the Act because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Therefore, they may not be legally marketed in the United States without approved New Drug Applications (Section 505 of the Act). These products are also misbranded within the meaning of Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use.

The above violations are not meant to be an all-inclusive list of deficiencies 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.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed

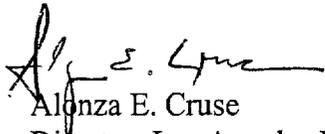
Letter to Mr. Katke, Metagenics, Inc.

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within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Mr. Larry Stevens, Compliance Officer, U.S. Food and Drug Administration, 19900 MacArthur Blvd., Suite 300, Irvine, CA 92612.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is written in a cursive style with a long horizontal stroke at the end.

Alonza E. Cruse
Director, Los Angeles District