

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 24, 1999

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207  
Telephone: 313-226-6260**WARNING LETTER**  
DET-99-12

Michael W. Marlin, Chief Executive Officer  
Jackie Marlin, President  
Easy Way International, Inc.  
5430 Commerce Square Circle, Suite E  
Indianapolis, Indiana 46237

Dear Mr. and Mrs. Marlin:

This letter is in reference to your firm's marketing and distribution of Gentle Changes with Activin essential balancing cream, EZ Cleanse Capsules, EZ Calm capsules, EZ Energy, EZ Greens, EZ Omega 3+, and EZ OPC. Promotional material (labeling) makes therapeutic claims which cause the products to be drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of claims appearing in the most recent product catalogs include the following:

**Gentle Changes with Activin essential balancing cream:**

". . . help with hot flashes, night sweats, insomnia, PMS mood swings, depression, weight gain, heavy and/or irregular periods, water retention, fibrocystic breast disease, bone fragility and osteoporosis . . . protects against the undesirable side effects of estrogen, such as . . . increased uterine fibroids, increased risk of uterine cancer and breast fibrocysts, as well as increased risk of breast cancer . . . powerful effect on breast and uterine cancer cells . . . for prevention of osteoporosis . . . migraines . . . alternative to prescription hormone replacement therapy . . . improved memory, less muscle cramps, improved skin (less acne, seborrhea, rosacea, psoriasis, keratoses) . . . protects against the undesirable side effects of estrogen such as . . .," " . . . relieving the following symptoms: hot flashes, night sweats, PMS, bloating, water retention, irregular or heavy periods, insomnia, mood swings, weight gain, fibrocystic breast disease, as well as loss of sex drive."

**EZ Calm capsules:** ". . . for . . . alcohol and drug addiction and attention deficit disorder . . . Unexplained depression . . . ADD, ADHD, . . . alcoholism . . . reduction of high blood pressure."

**EZ ENERGY:** ". . . help my depression"

**EZ OPC:** ". . . prevent the release of histamine which may result in decreased irritations associated with allergies, asthma and hay fever . . . support the repair of collagen protein that may be associated with inflammation, sprain or tendonitis; and to prevent and relieve structural breakdown of the collagen tissues

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that may be associated with phlebitis, polyarteritis, varicose veins and skin bruising."

The products are "new drugs" because there is no evidence that they are generally recognized as safe and effective for their intended use [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

The drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act]. The labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We are aware of the following products and claims appearing in your catalog. These claims may also cause the products to be new drugs and misbranded drugs.

**EZ GREENS:** ". . . may decrease the risk for cardiovascular disease, osteoporosis and estrogen dependent cancers . . . decreases the risk factors associated with cancer, heart disease and suppressed immunity."

**EZ OMEGA 3+:** ". . . help prevent arteriosclerosis and hardening of the arteries the high risk factors associated with strokes and heart attacks; help suppress chronic pain and inflammation often associated with arthritis, allergies or PMS . . . ."

**EZ Cleanse capsules:** ". . . destroys and expels nutrient-draining worms, parasites . . . disinfects and eliminates poisons and toxins in the body while soothing and promoting healing of the digestive system."

We are also aware of additional unsubstantiated claims for Gentle Changes, appearing on your web site. These claims, similar to those listed in the Gentle Changes product brochure, further establish your intended use of this product as a drug.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and

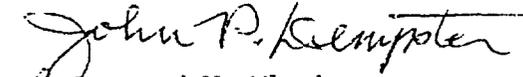
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for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the attention of Sandra Williams, Compliance Officer, Food and Drug Administration, at the above address.

Sincerely,

  
for Raymond V. Mlecko  
District Director  
Detroit District