



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

7/18
5-30-91

REGULATORY LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED 91-PHI-22

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4396

May 20, 1991

Address Reply to the Attention of:
Charles B. Thorne
Director, Compliance Branch

Mr. Hakan Cederberg
Ecomer, Inc.
13 N. 7th Street
Perkasie, Pennsylvania 18944

Dear Mr. Cederberg:

During an inspection of your firm conducted on October 18, and October 19, 1990, our investigator found that you market "STRIX Tablets", "EXSATIVA", "ECOMER" "ALKAGYCEROLS" (Shark Liver Oil), and "SUPER GLANDIN" (day creme and night creme).

The labeling and promotional material for your products states or suggests the following medical claims:

STRIX - (1). "has a strengthening effect on the walls of the small vessels, capillaries", (2). "for improved night vision and "tired eyes.", (3). "is produced from a standardized, controlled bilberry extract (Vaccinium myrtillus), giving an effective dose of anthocyanosides. These accelerate the production of rhodopsin (visual purple) in the retina."

EXSATIVA - (1). "It has been clinically tested to increase muscle strength, endurance time, performance." (2). "was originally developed as an anti-stress dietary supplement; however its general health-improving properties proved to be so powerful that it was decided to be taken through all developmental stages of a pharmaceutical product.", (3). "One of EXSATIVA's main ingredients is an oat extract... Oats... Rich in fiber, it lowers high blood cholesterol levels and can help prevent illness of the digestive tract.", (4). "was originally developed as an anti-stress dietary supplement.", (5). "Another essential ingredient is nettle extract... In ancient Greece... nettle seeds were a popular aphrodisiac."

(GEN.)	RELEASE	SPEC.
FILE	DATE 5/24/91	
C.O.	E. A. McCARRON	

Page 2 - Mr. Hakan Cederberg
Ecomer Inc.
Perkasie, Pennsylvania
(Regulatory Letter)

ECOMER ALKYLGLYCEROLS (Shark Liver Oil) (1). "While the body make alkylglycerols, taking Ecomer capsules helps ensure that the body has a sufficient level of alkylglycerols. Alkylglycerols are involved in the production of white blood cells, which are system."

SUPER GLANDIN - (Day creme and night creme) also contains false medical claims: (1). "Super Glandin contains Gamma Linolenic Acid (GLA)...The skin can then directly turn GLA into very useful prostaglandins, and it is these prostaglandins that keep the skin in good condition and protect the skin against premature aging, wrinkles, etc." (2). "It is also true that Super Glandin works as a natural "facelift" and diminishes wrinkles," (3). "Super Glandin has an extremely good effect on dry skin, as well as certain areas of eczema and acne problems.", (4). "Because of its high GLA content...(a). Increases bloodflow through the superficial vessels of the skin (capillaries). As a result of the flow of nutritional substances to the outer layer of the skin increases. (b). Builds up and strengthens the cell walls." (c). "Protects your skin from dangerous ultraviolet (UV) radiation."

These products fall within the meaning of section 201(g) of the Federal Food Drug and Cosmetic Act because they are drugs intended for use in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body of man. Further, we are unaware of any substantial scientific evidence which documents these drugs are generally recognized as safe and effective for the above referenced conditions.

Therefore, they are new drugs within the meaning of Section 201(w) and marketing of these drugs is a violation of the Federal Food, Drug and Cosmetic Act (Act) as follows:

Section:

505(a)

Brief Description:

The articles, "STRIX Tablets"
"EXSATIVA", " ECOMER
ALKYLGLYCEROLS" (Shark Liver Oil)
"SUPER GLANDIN (day creme and
night creme)" are drugs within the
meaning of Section 201 (g) of the
Act which may not be introduced or

Page 3 - Mr. Hakan Cederberg
Ecomer Inc.
Perkasie, Pennsylvania
(Regulatory Letter)

delivered for introduction in interstate commerce under section 505(a) of the Federal Food, Drug Cosmetic Act, since they are new drugs within the meaning of section 201(p) of the Act and no approval of an application filed pursuant to section 505(b) is effective for such drugs.

502(a)

The articles "STRIX Tablets", "EXSATIVA", "ECOMER ALKYLGLYCEROLS" ("Shark Liver Oil"), and "SUPER GLANDIN" (day creme and night creme) are misbranded in that the labeling is false and misleading by representations and suggest that there is substantial evidence that the articles are safe and effective for the prevention or treatment of the conditions identified above.

502(f)(1)

The articles of drug are misbranded in that the labeling fails to bear adequate directions for use, and the labeling is not exempt from this requirement under Regulation 21 CFR 201.115 since the articles are new drugs within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.

The following pertain to the product "EXSATIVA"

403(a)(1)
21 CFR 101.9(c)(7)(v)

The labeling claims (brochure) for oats "high content of protein", "vitamins B, D and E and minerals"; for nettles "rich in vitamins A and (betacarotene), C and K, proteins; ...and minerals such as calcium, magnesium and iron", "high iron

Page 4 - Mr. Hakan Cederberg
Ecomer Inc.
Perkasie, Pennsylvania
(Regulatory Letter)

content"; for sea buckthorn "beta-carotene, vitamins B1, B2, B6, E"; and for excipients "vitamin C" falsely represents that this food is a significant source of these nutrients. No claims may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 % of the U.S.RDA in a serving.

The labeling claims (brochure) for oats "more zinc than any other plant"; and for sea buckthorn "very high vitamin C content which surpasses the vitamin C content of all known fruits and vegetables" falsely represents that this food is nutritionally superior to another food. No claim may be made that a food is nutritionally superior to another food unless it contains at least 10% or more of the U.S.RDA of the claimed nutrient per serving.

The labeling claims for "energy" and "energizing effect" are false and misleading since a serving of 0.033 oz. of the product would have an insignificant amount of calories.

The labeling claim as a "dietary supplement" is false and misleading in that a single serving fails to provide 50% or more of the U.S.RDA of any vitamin or mineral.

The labeling claims (brochure) for chlorophyll, flavonoids and pectins falsely represent dietary properties when such properties are of no significant value or need in human nutrition.

Page 5 - Mr. Hakan Cederberg
Ecomer Inc.
Perkasie, Pennsylvania
(Regulatory Letter)

403(f)
21 CFR 101.2 (c)
101.2 (e)

The list of ingredients, name and address of the distributor fail to appear in one place without intervening material.

403 (1) (1)
21 CFR 101.3 (b) (3),
101.18 (b) and 102.5 (a)

The label fails to bear a statement of identity expressed in terms of the common or usual name of the food or its characterizing properties. The label designates, on the principal display panel, only one ingredient but not all three ingredients which are designated elsewhere in the labeling.

The labeling representations (brochure) for "enhanced longevity", "red blood cell building process", "rise in blood pressure was less severe" and "diastolic pressure became lower" falsely represent this product as adequate or effective for those labeled conditions.

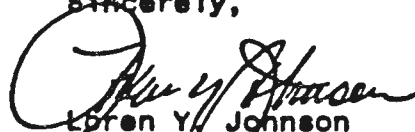
It is your responsibility to assure that all products distributed by your firm are in compliance with the requirements of the Federal Food Drug, and Cosmetic Act.

If such action is not taken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food Drug, and Cosmetic Act provides for seizure of illegal products, and enjoining the manufacturer or distributor from distribution of illegal products (21 U.S.C. 332 and 334).

Page 6 - Mr. Hakan Cederberg
Ecomer Inc.
Perkasie, Pennsylvania
(Regulatory Letter)

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of the referenced products.

Sincerely,



Loren Y. Johnson
District Director
Philadelphia District

EAM/YH/dmh

