DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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JUL 31 2003

Mr. Terry A. Yimin
CEO/President
Essere Corporation
Jonnet Building
Suite 409
4099 William Penn Highway
Monroeville, Pennsylvania 15146

Dear Mr. Yimin:

This is in response to your letter to the Food and Drug Administration (FDA) dated July 15, 2003 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Essere Corporation is making the following claims, among others, for the product **Flex-Rx Topical Analgesic**:

> "For external use only."
> "For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains."

This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

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An article that is applied externally to the skin is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...
>
> The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product that is applied to externally to the skin is not subject to regulation as a dietary supplement because it is not "intended for ingestion" and is a drug under 21 U.S.C. 321(g)(1)(C) because it is an article (other than food) intended to affect the structure or function of the body and under 21 U.S.C. 321(g)(1)(B) because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (i.e., to treat pain associated with diseases such as arthritis and injuries such as sprains, strains, etc.). If you intend to market this product as a drug, 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 20852.

Dedicated to helping others through natural skin care, nutritional and remedy care.

Essere Corporation
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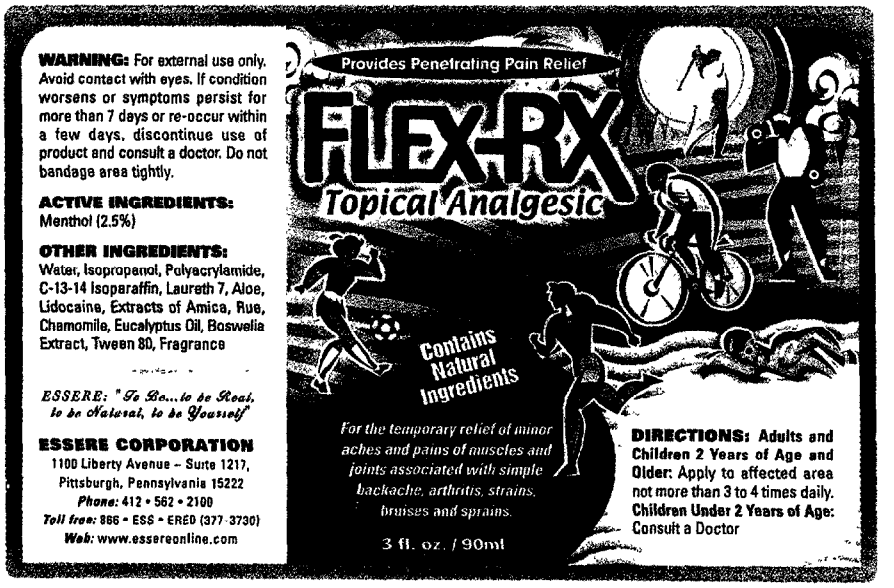
July 15, 2003

Food and Drug Administration
Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

JUL 2 2 2003

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403 (r) (6) (21) U.S.C. 343 (r) (6) of the Federal Food and Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Essere Corporation, Jonnet Building-Suite 409, 4099 William Penn Highway, Monroeville, PA 15146, within the past 30 days commenced marketing a Topical Analgesic bearing the following statement(s) on the label and or labeling.



The undersigned certifies that the information contained in this notice is complete and accurate and that Essere Corporation has substantiation that the statement is truthful and not misleading.

Sincerely,

Terry A. Yimin
CEO/President

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