WWK 10-17-89

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mid-Atlantic Region

Food & Drug Administration
61 Main Street
West Orange, NJ 07052

Telephone (201)

October 11, 1989

REGULATORY LETTER

Richard Breitbarth, President
Biophase Systems International
314 West First Avenue
Roselle, New Jersey 07203

File No: 90 NWK-2

Dear Mr. Breitbarth:

During an inspection of your firm on May 4,1989 et al, our investigator documented that you are engaged in the marketing of Biocon 100 Contrapathic Douche, Genesis Contrapathic Douche, and Paracan-144 Dietary Supplement.

Our review of the labeling for Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche indicates that they contain aloe vera, tea tree oil, and potassium sorbate in addition to other ingredients, and are intended for use as vaginal douche products to control the overgrowth of problematic vaginal flora. Based on their intended use we would regard these products to be drugs as this term is defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act. We are not aware that the subject drugs or any similar over-the-counter vaginal douche products have been marketed in this country on or before December 4, 1975.

Additionally, we are unaware of any evidence that Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche are generally recognized as safe and effective for the treatment or prevention of the disease conditions recommended or suggested in their labeling. We, therefore, regard the marketing of Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche to be in serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
505(a)	The articles Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug, and 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(f)(1) — The articles of drug are also misbranded in that their labeling fails to bear adequate directions for use and they are not exempted 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.

502(e)(1) — Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche preparations are misbranded in that their labeling fails to bear the established name as defined in Section 502(e)(3)(c) since they do not represent the common or usual names of the actual ingredients.

502(o) — Biocon 100 Contrapathic Douche and Genesis Contrapathic Douche are misbranded in that they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act.

Further, the two vaginal douches are drugs and may be considered to be adulterated within the meaning of Section 501(a)(2)(B) if the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practice (21 Code of Federal Regulations, Parts 210 and 211) to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics which they purport on are represented to possess.

Our review of the labeling for Paracan-144 indicates that it is "***Derived from grapefruit seeds, supplies Vitamin C, unsaturated fatty acids, 19 amino acids, and Biotrose (a natural dextrose) in a vegetable glycerine base."

We regard the marketing of Paracan-144 to be in violation of the Federal Food, Drug and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1) 201(n)	Paracan-144 is misbranded in that it's labeling makes a nutritional claim and its labeling lacks the mandatory nutritional information required by 21 CFR 101.9.
403(i)	Paracan-144 is misbranded in that it's label fails to bear a complete statement of ingredients by common or usual name in descending order of predominance by weight as required by 21 CFR 101.4(a).

We question the use of the term "Dietary Supplement" on the label of the product. No specific information was provided during the inspection regarding the nutrient content of the product. However, ascorbic acid is declared on one of the labels (identified as label currently on the market) and a claim for vitamin C is made on another label (identified as new labeling not yet on the market as of 5/8/89). The product may be labeled as a dietary supplement of a specific vitamin or mineral only if it contains 50% or more of the U.S. RDA of the vitamin or mineral per serving.

"Botanical seed extract" and "Paracan 144 derived from grapefruit seeds" are not appropriate common or usual names for a food or food ingredient. We also question the food additive status of "grapefruit seed extract." Our concern regarding the food additive question is raised on the absence of data describing (1) the extracting process, (2) the extracting solvent, (3) specific identity of the substance(s) extracted, (4) the intended use of the substance(s) extracted, and (5) the amount of residue remaining in/on the extracted substance(s) from the extracting solvent.

There is no regulation which provides for the safe use condition of "grapefruit seed extract", neither is there a body of knowledge which asserts that grapefruit seed extract has been safely consumed as food by humans prior to 1958. Further, we are aware of no scientific data which establishes that "grapefruit seed extract" is safe. The food additive provisions of the act require that unless at least one of the conditions cited above are met, the substance under question is deemed adulterated under Section 404(a)(2)(C) because it is deemed unsafe under Section 409.

You may wish to provide the information enumerated above for our review in support of your contention that the grapefruit seed extract is safe for human consumption. Alternately, you may wish to file a petition to establish, on the basis of scientific procedure, that grapefruit seed extract is safe.

The most recent label (identified as new labeling not yet on the market as of 5/8/89) bears the claim, "supplies....unsaturated fatty acids." Title 21 CFR 101.25(c)(1) currently permits a claim regarding fatty acid content to be made if the food contains 10% or more fat on a dry weight basis and not less than 2 grams of fat per serving. If the product does not meet this criteria, the fatty acid claim must be deleted.

The name "Biotrose" is not an appropriate common or usual name for a food ingredient. The most recent label bears the statement, "Biotrose (a natural dextrose)." If the "Biotose" is simply dextrose, it should be declared as such in the ingredient statement. If the "Biotrose" contains two or more individual ingredients, the common or usual names of these ingredients must be declared in the ingredient statement on the label.

The specific common or usual names of the sources of the "Trace Elements" in the product must be declared in the ingredient statement on the label. The most recent label bears the claim, "supplies...19 amino acids." It is unclear whether these amino acids are inherent or are added to the product. In either case, the claim is misleading. If the amino acids are inherent, the amounts present in 2-4 drops of the product added to water would be insignificant in the diet. If the amino acids are added as discrete ingredients, you are advised that 21 CFR 172.320 does not permit the addition of amino acids either singly or in combination with dietary supplements.

The above enumeration of violations is not intended to be an all inclusive list of deficiencies.

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions as provided by law. These include, seizure and/or injunction.

Please notify this office in writing, within ten (10) days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your reply should be sent to the Food and Drug Administration, Newark District Office, 61 Main Street, West Orange, New Jersey 07052, Attention: Lester H. Mathis, Compliance Officer (201) 645-6470.

Very truly yours,

Matthew Lewis

MATTHEW H. LEWIS
District Director
Newark District Office

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

LHM:np