

W4447 6-16-87

HFW-35
FOI



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915
~~303-837-4018~~

June 2, 1987

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary A. Barnes, President
Nature-All Formulas, Inc.
95 S. Mountainway Drive
Orem, Utah 84058

REGULATORY LETTER

Dear Mr. Barnes:

This is in regard to your marketing of Colostrum Tablets made for you by Flair Company, Inc., Worthington, Minnesota. Labeling distributed by your firm promotes Colostrum Tablets as nutritional support for a weakened or impaired immune system with brochures entitled, "Colostrum Ancient Medicine for Our Time" (Nature-All); "Colostrum Ancient Medicine for Our Time" by Dr. Robert R. Plymate; and "The Colostrum Report" by the International Institute of Nutritional Research.

Because such statements represent and suggest that the above mentioned drug is intended to be used in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or any function of the body of man, this product is a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial evidence which demonstrates that this drug is generally recognized as safe and effective for its intended use. Accordingly, continued marketing of this drug is a serious violation of the Act as follows:

<u>Section</u>	<u>Brief Description</u>
502(a)	The aforesaid article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the article is safe and effective for the above specified conditions.
502(f) (1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for the use for which the article is represented or suggested (as described above), and it is not exempt from this requirement under regulation 21 CFR 201.115 since the article is a new drug within the meaning of section 201(p) and no approval of an application filed pursuant to section 505(b) is effective for this drug.

Mr. Gary A. Barnes, President
Page 2

The article of drug is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which it is offered are not amenable to self diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use this drug safely and for the purposes for which it is intended.

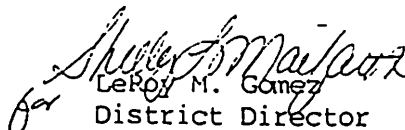
505(a) The article is a drug within the meaning of section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Federal Food, Drug, and Cosmetic Act, since it is a new drug within the meaning of section 201(p) of the Act and no approval of an application filed pursuant to section 505(b) is effective for such drug.

The charges and the products contained in this letter are not meant to be all-inclusive. It is your responsibility to ensure that all products manufactured, distributed, and/or labeled by your firm are in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act.

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 actions as provided by law. Please advise this office in writing, within ten days (10) of receipt of this letter, of the steps you have taken to correct these violations. Your response should be directed to:

Ms. Shelly L. Maifarth, Compliance Officer
U.S. Food and Drug Administration
500 U.S. Customhouse
Denver, Colorado 80202

Sincerely,


Leroy M. Gomez
District Director

cc: Dr. Gary Whitley

bcc: HFA-224 HEW-35 (FOI) Inj. File HFN-300 (Auer)
EI R/F CB/f/u 6/12/87 Printout SLM Chrono
IB-f/u/by IB to be indicated after firm's response
DRA--State Agency--FOR OFFICIAL USE ONLY