REGULATORY LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Feb 26 1987

Authur Rudolph
President
Nature's Bounty, Inc.
90 & 105 Orville Drive
Bohemia, NY 11718

Dear Mr. Rudolph:

This is reference to Ener-B, a nasal gel. The product is labeled to contain 400 mcg. per 0.1cc dose.

Investigation reveals that Ener-B is offered as a safe and more effective way to take Vitamin B-12; Ener-B delivers Vitamin B-12 directly into the bloodstream; that Ener-B delivers the highest B-12 blood levels available without prescription; that Ener-B delivers up to 10 times more B-12 than conventional tablets; that Ener-B achieves maximum B-12 blood levels up to 16 times faster than tablets.

Based on this method of administration and the intended use, we regard Ener-B to be a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). We are unaware of any scientific evidence which demonstrates that Ener-B is generally recognized among experts as safe and effective for its intended use or any other therapeutic use. Therefore, we regard Ener-B to be a new drug as defined by section 201(p) of the Act. Accordingly, continued marketing of this drug is a serious violation of the Act as follows:

SECTION	BRIEF DESCRIPTION
505(a)	The article, "Ener-B", 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 a drug.
502(f)(1)	The aforesaid article of drug is misbranded in that its labeling fails to bear adequate directions for use for the conditions for which the article is represented and 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 the said article of drug.

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 this drug product. If prompt corrective action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and/or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334). Your reply should be directed to:

Robert Heller
Chief, OTC Compliance Branch (HFN-312)
Center for Drugs and Biologics
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We request that your reply include:

1) An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2) An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3) An estimate of the amount of the drug that is in inventory under your control and of the amounts that remain in channels of distribution outside of your control.

4) The date of discontinuance in the event that you have already discontinued marketing this drug product.

5) Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Sincerely yours,

Daniel Michels
Director
Office of Compliance
Center for Drugs and Biologics