DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Nashville District Office
Southeast Region
297 Plus Park Blvd.
Nashville, TN 37217

August 23, 1988

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen L. Lucas, President
Manna Products, Inc.
224 East 20th Street
Covington, KY 41014

REGULATORY LETTER
Our File: 88-NSV-36

Dear Mr. Lucas:

This letter is in reference to the marketing by your firm of the line of Manna herbal extract products and one Manna product which is an extract of bee pollen. Promotional material (labeling) distributed with these products states or suggests that they are useful and effective in the treatment of: candida, viruses and the immune system in general (Formula 1000); eliminating cholesterol, plaque and diseases of the blood (Formula 1100); internal or external ulcers (Formula 2800); leukemia, sarcomas and carcinomas (Formula 3000); cataracts (Formula 4000); diptheria, scarlet fever, smallpox and Bright's disease (Formula 5200); and infections (Formula 5000).

Because such labeling includes statements which represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which documents that these drugs are generally recognized as safe and effective for the above referenced disease conditions or any other disease conditions. The drugs are, therefore, new drugs within the meaning of Section 201(p). Accordingly, marketing of these drugs is in violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The articles of drug are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the treatment of the previously listed disease conditions.
502(f)(1)	The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the treatment of the previously listed disease conditions for which the articles are represented or suggested, and they are

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 any application filed pursuant to Section 505(b) is effective for these drugs.

The articles of drug are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5, since the conditions for which they are 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 these drugs safely and for the purposes for which they are intended.

505(a) The articles 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 any application filed pursuant to Section 505(b) is effective for these drugs.

The violations and products listed above are not meant to be all inclusive. It is your responsibility as a drug distributor to ensure that all of your present products, as well as any similar products intended for further distribution, are the subject of approved new drug applications wherever appropriate and that the products are properly labeled for their intended uses.

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 these drug products. If such corrective action is not promptly undertaken, 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 or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should include:

1. An estimate of the quantities of the drugs 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 amounts of the drugs that are in inventory under your control and your estimate of the amounts in distribution channels outside your control.

4. The date of discontinuance in the event that you have already discontinued marketing these drug products.

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

Your reply should be directed to Frank J. Jancarek, Compliance Officer, at this address.

Sincerely,

Hayward E. Mayfield
Director, Nashville District

FJJ/cmc

bcc: HFN-304 HFA-224 HEM HFR-SE1 (Kinslow) LEX-RP Thru WHO/JAV
EI FJJ RL/F R/F HFI -35 (Purged) FOI (Purged)