Food and Drug Administration
Rockville MD 20857

REGULATORY LETTER

JUL 25 1990

Barbara W. Larkins, President
Health Care Products, Inc.
19235 U.S. Highway 41 North
Lutz, Florida 33549

Reference No.: 90-HFD-312-02

Dear Ms. Larkins:

This letter is written in reference to the marketing of Cal-Ban 3000 labeled as containing "Specially prepared ground endosperm of Cyamopsis Tetragonolobus", i.e., guar gum.

Promotional material (labeling) distributed with the product represent and suggest that it is useful for, among other things, weight control. Based on the claims for weight control we regard Cal-Ban 3000 to be a drug within the meaning of 201(g) of the Federal Food, Drug, and Cosmetic Act.

Under the agency's general regulatory policy governing OTC products during the pendency of the OTC Review, OTC products may be permitted to be marketed without the risk of regulatory action provided:

1. The product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC Review (May 11, 1972), a date that was then extended to on or before December 4, 1975 (21 CFR 330.13).

2. Such product does not constitute a hazard to health.

3. The product formulation is not regarded to be a prescription drug within the meaning of 503(b).

4. It is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

The Food and Drug Administration is aware of at least 17 adverse reaction reports of esophageal obstruction associated with the use of Cal-Ban 3000. Ten of the cases required hospitalization and one person eventually died as an indirect result of the esophageal obstruction. The agency has also received complaints that consumers have found it necessary to seek medical attention to resolve other health problems related to the use of Cal-Ban 3000. Based on the evaluation of these reports the agency has concluded that a health hazard exists which warrants the immediate removal of Cal-Ban 3000 from the marketplace.

Accordingly, marketing of Cal-Ban 3000 is in violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The article, Cal-Ban 3000, is misbranded in that its labeling is false and misleading by representation and suggestion that there is substantial scientific evidence to establish that the article is safe and effective for use as an appetite suppressant or weight control.
502(f)(1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for use for the condition for which it is being offered 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.
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) of the Act is effective for such a drug.

We request that you immediately cease distribution of Cal-Ban 3000 and related promotional materials, and that you provide an immediate response to this request stating the corrective action you have taken or will take to correct the above violations. This response should be confirmed in writing within 5 days. If stocks of this product and promotional materials remain in trade channels at this time, we request that they be immediately recalled to the retail level. If distribution is not ceased immediately and corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The 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).

Sincerely,

Ronald G. Chesemore

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs (HFC-1)