

MAR 26 1996

Jonathan W. Emord
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1050 Seventeenth Street, NW, Suite 600
Washington, DC 20036

Dear Mr. Emord:

This is in response to your letter of March 14, 1996 which responded to a letter of March 6, 1996 from the Food and Drug Administration (FDA) objecting to a claim being made under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). The claim in question is being made by your client, Pure Encapsulation, Inc. on a product called "Folic Rinse."

You state that "the agency presumes erroneously that counsel for the maker of the product is in fact the manufacturer of the product." The agency is aware that Pure Encapsulation, Inc. is the manufacturer of the product. However, no address was given for this manufacturer, so the only way we could make your client aware of our concerns was to correspond with the submitter of the original submission to the agency. If you would wish that we communicate directly with your client, provide an address for Pure Encapsulation, Inc.

Your letter takes exception to the agency's conclusion that Folic Rinse "does not appear to meet the definition of a dietary supplement in section 201(ff)(2)(A)(i) of the act, which states that the term 'dietary supplement' means a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form." You contend that the agency has assumed "that the term 'ingestion' within the meaning of section 411(c)(1)(B)(i) of the act is synonymous with 'digestion.'"

The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 393, (E.D.N.Y.) aff'd, 72 F.3d 285 (2d Cir. 1995) which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as 'the introduction of food and drink into the stomach'); Webster's Third New International Dictionary (1976) (defining ingestion as 'the taking of material (as food) into the digestive system.').

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for

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ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Thus, the agency does not contend that Folic Rinse is not a dietary supplement because it is not "digested," rather, it is not a dietary supplement because it is not "ingested" (i.e., introduced into the stomach or gastrointestinal tract or swallowed). As stated in our previous letter, Folic Rinse does not meet the definition of a dietary supplement in section 201(ff)(2)(A)(i) of the act.

United States v. Ten Cartons, Ener-B Nasal Gel, *supra*, also addressed FDA's position on sublingual administered products when it stated:

[w]hile it is true that no enforcement action has as yet been taken against sublinguals, the FDA has never taken the position that sublingual tablets are foods.

You also disagree with the agency's conclusion that it appears that this product is intended for drug use within the meaning of section 201(g)(1) of the act. Your previous submission stated that your client is making the following statement of nutritional support for the product "Folic Rinse."

In solution form, folic acid nutritionally supports the health of gingival tissue. Locally applied folic acid solution promotes healthy tissue by reducing gingival exudate from gums. Folic Rinse provides optimal nutritional support for gingival health.

Section 201(g)(1) of the act states that a "drug" is an "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals." We point out that section 403(r)(6) of the act makes clear that a statement included in the labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for "Folic Rinse" suggests that this product is intended for at least one of these purposes, in that it claims to promote "healthy tissue by reducing gingival exudate from gums." "Exudate" is defined by Stedman's Medical Dictionary (24th Ed.1982) as "any fluid that has exuded out of a tissue or its capillaries, more specifically because of injury or inflammation." This statement implies that "folic rinse" is intended to cure, mitigate, or treat gum disease.

Thus, FDA's position is unchanged. "Folic Rinse" is not a dietary supplement under section 201(ff)(2)(A)(i) of the act because it is not intended for ingestion (i.e., is not swallowed and is not introduced into the stomach or gastrointestinal tract). Furthermore, it appears that this product is intended for drug use within the meaning of section 201(g)(1) of the act because the claim "promotes healthy tissue by reducing gingival exudate from gums"

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implies that this product is intended to cure, mitigate, or treat gum disease.

As stated in our previous letter, if you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Sincerely yours,

John Gordon
Acting Director,
Division of Program and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200