



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
College Park MD 20740

NOV 20 2009

Eric M. Wingerter
President
Pan American Labs, L.L.C.
4099 Highway 190
Covington, Louisiana 70433

WARNING LETTER

Re: CFSAN-OC-10-02

Dear Mr. Wingerter:

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites at the Internet addresses <http://www.neevoprenatal.com> and <http://www.pamlab.com> in November 2009. Your Neevo caplets prenatal product is labeled as a "medical food," and the labeling claims on your websites represent the product as a medical food for the dietary management of those women under a physician's treatment for vitamin deficiency throughout pregnancy, postnatal and the lactating periods. In addition, your product is indicated for the distinct nutritional requirements of older obstetrician (OB) patients, high-risk pregnancies and DB patients with the methylenetetrahydrofolate reductase (MTHFR) folate polymorphism. This product is misbranded under Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343(a)(1)], because the label is false and misleading in that the product is labeled and marketed as a medical food but does not meet the statutory definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in 21 C.F.R. 101.9(j)(8).

The Orphan Drug Act defines "medical food" as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The regulation in 21 C.F.R. 101.90)(8) sets forth criteria to clarify the statutory definition of a medical food.

Specifically, this regulation provides that a food is a medical food only if:

- i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;
- ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
- iii. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- iv. It is intended to be used under medical supervision; and
- v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

FDA considers the statutory definition of "medical food" to narrowly constrain the types of products that fit within this category.¹ In addition to other criteria, medical foods must be for the dietary management of a specific disorder, disease, or condition for which there are distinctive nutritional requirements and must be intended to be used under medical supervision.² Patients with such a disorder, disease, or condition must have a limited capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or have other special medically determined nutrient requirements, which cannot be managed by the modification of the normal diet alone.³ Medical foods are not those simply recommended by a physician as part of an overall diet to reduce the risk of a disease or condition.⁴ As discussed further below, your prenatal product as reviewed on the aforementioned websites does not meet the regulatory criteria for a medical food.

Your website and the labeling information promotes your product for women planning to become pregnant, pregnant women (including older women), high-risk pregnant women, women with the MTHFR polymorphism (pregnant or nonpregnant), and post-partum women (including lactating women). Specifically, your product is intended for the dietary management of planned pregnancy (with/without MTHFR polymorphism), pregnancy (high-risk, in older women, with MTHFR polymorphism), postpartum and lactating women with distinctive nutritional requirements for specific nutrients, primarily L-Methyfolate and folic acid,⁵ and some or all of the following nutrients: vitamin E, vitamin C, vitamin D3, vitamin B1, vitamin B2, vitamin B3, vitamin B5, vitamin B6, vitamin B9, vitamin B12, biotin, calcium, iron, zinc, copper, and magnesium.

Pursuant to 21 C.F.R. 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. While your website states that the patients for whom your product is intended have "distinct nutritional requirements" and implies that diet alone *may* not supply the full amount of nutrients necessary for women who are pregnant,

planning to become pregnant, or are lactating, there is no available evidence that the levels of folic acid and other micronutrients necessary for pregnancy or lactation *cannot* be achieved by the modification of the normal diet alone. To the contrary, it is not only possible, but practicable for women who are pregnant, planning to become pregnant, or lactating to follow the 10M and FDA recommendations for folic acid intake within a normal diet. Specifically, given the widespread fortification of flours, breads, cereals, pastas, rice, and other grain products with folic acid as required by FDA regulations,^{6,7} and the variety of available foods in which folic acid occurs naturally,⁸ it would not be difficult for a woman to consume up to 800 micrograms of folic acid per day (FDA's recommended daily folic acid consumption for pregnant women) through diet alone. Furthermore, folic acid can be readily obtained from dietary supplements, such as folic acid tablets and multivitamins containing folic acid.

Because the Neevo prenatal product is intended for the dietary management of a condition with nutrient requirements that can be met through the modification of the normal diet alone, this product does not meet the regulatory criterion for medical foods set forth in 21 C.F.R. 101.9(j)(8)(ii). Accordingly, your product is misbranded within the meaning of Section 403(a)(1) of the Act because the label is false or misleading in that the product is labeled as a medical food but does not meet the definition of a medical food.

This letter may not be an all inclusive review of your websites or the products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the requirements of the Act and all applicable regulations. Failure to promptly correct violations may result in regulatory action being initiated by FDA without further notice, such as seizure and/or injunction.

In addition to the violation described above, we have a comment on the label for your Neevo prenatal product, which appears to contain an NDC number. For your information, NDC numbers are intended for uniquely identifying drugs and should not be used on the labels of products that are not drugs. The presence of an NDC number on a product that is not a drug may be a false or misleading representation that misbrands the product under Section 403(a)(1) of the Act.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your response should be directed to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement, 5100 Paint Branch Parkway (HFS-608), College Park,

Maryland 20740. If you have any questions regarding this letter, please contact Mr. Tien at the above address or by phone at 215-717-3705.

Sincerely,

/S/

Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New Orleans District Office

1 See 56 Fed. Reg. 60366, 60377 (Nov. 27, 1991); *see also* Guidance for Industry: Frequently Asked Questions About Medical Foods, May 2007.

2 See 21 U.S.C. § 360ee(b)(3); *see also* 56 Fed. Reg. at 60377.

3 See 21 C.F.R. 101.9(j)(8)(ii); *see also* 56 Fed. Reg. at 60377.

4 See 56 Fed. Reg. at 60377.

5 The Institute of Medicine recommends that adults consume at least 400 mcg folic acid each day, that lactating women consume at least 500 mcg each day, and that pregnant women consume at least 600 mcg each day. FDA recommends that adults consume 400 mcg folic acid each day and that pregnant and lactating women consume 800 mcg folic acid each day.

6 See 21 C.F.R. 136.115, 137.165, 137.185, 137.235, 137.260, 137.305, 137.350, 139.115, 139.122, & 139.155.

7 See Final Rule, Food Standards: Amendment of Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8781 (March 5, 1996). Under FDA's folic acid fortification program, which became effective January 1998, the agency requires manufacturers to add from 0.43 mg to 1.4 mg of folic acid per pound of product to enriched flour, bread, rolls and buns, farina, corn grits, cornmeal, rice, and noodle products.

8 Folate occurs naturally in a variety of foods, including liver; dark-green leafy vegetables such as collards, turnip greens, and Romaine lettuce; broccoli and asparagus; citrus fruits and juices; whole-grain products; wheat germ; and dried beans and peas, such as pinto, navy and lima beans, and chickpeas and black-eyed peas; *see also* "How Folate Can Help Prevent Birth Defects, FDA Consumer, February 1999.