

MAR 29 1996

Mr. Eugene I. Lambert
Covington & Burling
1201 Pennsylvania Avenue, NW
P.O. Box 7566
Washington, D.C. 20044-7566

Dear Mr. Lambert:

This is in response to your letter of March 13, 1996 which was a preliminary response to a March 6, 1996 letter from the Food and Drug Administration (FDA) to Randall Wisegarver, President, Pacific BioLogic. Your letter requested a meeting with FDA "to determine how the company [Pacific BioLogic] can appropriately segregate the claims of nutritional support permitted by section 403(r)(6) [of the Federal Food, Drug, and Cosmetic Act (the act)] from the equally appropriate identification of the relevant group of consumers for these dietary supplements, under section 411(c)(3)(A) of the act." We believe we can delineate the agency's position without the need for a meeting.

The notification from Pacific BioLogic received by FDA on January 26, 1996 indicated that Pacific BioLogic was giving notification to the agency in accordance with the requirement of section 403(r)(6) of the act. Section 403(r)(6) requires, in part, that if the manufacturer of a dietary supplement proposes to make a statement permitted by section 403(r)(6)(A) of the act "in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made." Thus, Pacific BioLogic notified the agency that it was marketing "dietary supplements" and making claims in accordance with section 403(r)(6) of the act.

In our previous letter we pointed out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. We further stated that the statements being made for these products suggest that they are intended for one of these purposes, in that: (1) RESIST claims to strengthen patients with reduced or compromised immune functions such as people with chronic fatigue syndrome, Epstein-Barr virus, and mentions RESIST for management of HIV; (2) RESIST 2 suggests that this product be used under conditions of increased heat or during mild outbreaks of symptoms and further states that "professionals working with patients with very pronounced or multiple heat conditions will prefer to use 3-4 capsules of Resist 2, 3 times per day;" (3) PRE COLD PLUS claims to supplement the diet when following a program designed to strengthen the body's defenses against the causes of cold and flu infections; and (4) COLD FREE 1 PLUS claims to supplement the diet when following a program designed to clear cold and flu conditions. Thus, these claims on the label or in the labeling of these products evidence that they are intended to prevent, cure, treat, or mitigate disease and the products are subject to regulation under the drug provisions of the act.

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Your letter of March 13, 1996 indicates that you wish these products to be considered "foods for special dietary use" as defined in section 411(c)(3) of the act which states, in part, "the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following: (A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease..." While we disagree that the claims discussed above simply reference the nutritional needs of persons with certain diseases, we would point out that "foods for special dietary use" as defined in section 411(c) of the act, are subject to the health claim provisions of section 403(r)(1)(B) of the act. Section 403(r)(1)(B) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations established under section 403(r)(1)(B) of the act. Pacific BioLogic has not petitioned the agency under 21 CFR 101.70 to authorize as health claims the claims that were the subject of the notification. Therefore, if considered to be "foods for special dietary use," these products are misbranded under section 403(r)(1)(B) of the act as well as being unapproved new drugs.

If Pacific BioLogic wishes to make the claims cited above, they should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855 or petition the agency to issue a regulation authorizing a health claim under the provisions of 21 CFR 101.70. These claims are unlawful and misbrand these products unless the products become approved new drugs or these specific health claims are authorized by the agency.

Please contact us if we may be of further assistance.

Sincerely yours,

John Gordon
Acting Director,
Division of Programs 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, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200