DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 16 2003 6492 '03 OCT -2 A9:37

Gary Moore
President
Colorado Biolabs, Inc.
Post Office Box 125
Cozad, Nebraska 69130-0125

Dear Mr. Moore:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 18, 2002 requesting that we reconsider our conclusion set forth in a letter to you dated December 26, 2000. In that letter, we disagreed with your assertion that your product Heme Iron Polypeptide (HIP) was a peptone within the scope of 21 CFR 184.1553. In your current letter, you ask us to reconsider that conclusion and to designate it as a peptone affirmed as generally recognized as safe (GRAS) under section 21 CFR 184.1553.

Your original submission of September 26, 2000 was made pursuant to 21 U.S.C. 350b(a)(2); namely, it was a submission made for a new dietary ingredient that you intended to use in dietary supplements. Under the Act, a submission made pursuant to that section must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. Whether the substance is or is not a substance within the scope of substance defined by a particular GRAS affirmation regulation is not material to reaching a determination that a substance is not adulterated under 21 U.S.C. 342(f)(1)(B). Therefore, with respect to reaching a conclusion as to whether HIP may be used in a dietary supplement as a dietary ingredient defined in 21 U.S.C. 321(ff)(1), there is no reason for the agency to consider whether it is or is not a substance that is within the scope of 21 CFR 184.1553 and we decline to do so.

However, the fact that HIP may lawfully be used in dietary supplements does not establish that it may lawfully be used as an ingredient in other foods. Unlike dietary ingredients used in dietary supplements, ingredients used in conventional food must meet different standards. Under the Act, any substance added to a food sold in the U.S. must be used in accordance with a food additive regulation which specifies the conditions under which the additive may be used safely, except a regulation is not needed if it is GRAS for its intended use. Any questions you have about the use of HIP in foods other than dietary supplements, including whether it is a substance that is within the scope of 21 CFR 184.1553, must be directed to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

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Please contact us if you have further questions concerning this matter.

Sincerely yours,

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition