



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2432 6 APR 10 P1:59

MAR 29 2006

Jeffrey L. Williams, MD, MS Bioengineering
Member
Advanced Cardiac Life Sciences, LLC
4885-A McKnight Road
Suite 405
Pittsburgh, Pennsylvania 15237

Dear Dr. Williams:

This is in response to your letter of March 10, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Advanced Cardiac Life Sciences, LLC is making the following claim for the product **Cardioavance™**:

“Cardioavance™ proper diet, and exercise lowers a woman’s total cholesterol and LDL (bad) cholesterol an average of 11%.^{1,2}”

21 U.S.C. 343(r)(6) 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. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease.¹ This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

¹In the preamble to the January 6, 2000 final rule on structure function claims (65 FR 1000 at 1019) FDA stated that “FDA continues to believe that “lowers cholesterol,” however qualified, is an implied disease claim.”

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Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

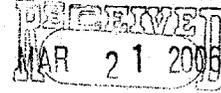
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Philadelphia District Office, Office of Compliance, HFR-CE140



10 March 2006

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied
Nutrition, Food and Drug Administration,
5100 Paint Branch Pkwy.
College Park, MD 20740
301-436-2375



AMS 2006-2281

Sir or Madam:

Advanced Cardiac Life Sciences, LLC files this notification of statements of nutritional support pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act. This notification also includes the certification required by 21 CFR Part 101.93(a)(3).

1. Name and Address of Supplement Distributor: Advanced Cardiac Life Sciences, LLC, 4885-A McKnight Road, Suite 405, Pittsburgh, PA 15237
2. Text of the Statement that is Being Made: "Cardioavance™, proper diet, and exercise lowers a woman's total cholesterol and LDL (bad) cholesterol an average of 11%."^{1,2}
3. Name of the Dietary Ingredient or Supplement that is Subject of the Statement: Cardioavance™.
4. Name of the Dietary Supplement (including Brand Name) in Whose Labeling the Statement Occurs: Cardioavance™
5. Substantiation information is on file in the sponsor's office. The company member that can certify same is Jeffrey L. Williams, MD, MS, Member.

Furthermore, it is hereby certified that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Regards,



Jeffrey L. Williams, MD, MS Bioengineering
Member
Advanced Cardiac Life Sciences, LLC

¹Cleeman JI (Corresponding Author), Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)," JAMA, V. 285, No. 19 (May 16, 2001), pp. 2486-2497.

²Varady KA, Jones PJH, "Combination Diet and Exercise Interventions for the Treatment of Dyslipidemia: an Effective Preliminary Strategy to Lower Cholesterol Levels?" Journal of Nutrition, V. 135 (2005), pp. 1829-1835.

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