

CERTIFICATE

In accordance with the Provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that the copy attached (as listed below) is a true copy of material on file in the Food and Drug Administration, Department of Health and Human Services, and is a part of the official records of said Administration and Department.

To Whom It May Concern letter

March 18, 2009

From Jeremy Mihalov

regarding: Special Nutrients, Inc.

**MYCO-AD
MYCO-AD D-F
MYCO-AD A-Z**

2. In witness whereof, I have pursuant to the provisions of Title 42, United States Code, Section 3505, and section 1410.20 of the Food and Drug Administration Staff Manual Guide, hereto set my hand and cause the seal of the Department of Health and Human Services to be affixed this 18 day of March, 2009.

Laura M. Tarantino

Laura M. Tarantino, Ph.D.
Director,
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

By direction of the Secretary
of Health and Human Services

"This certificate expires on March 18, 2012"



MAR 18 2009

TO WHOM IT MAY CONCERN

We have reviewed correspondence on behalf of

Special Nutrients, Inc.
2766 Douglas Road
Miami, Florida 33133

concerning the following products which are under the jurisdiction of the Food and Drug Administration (FDA) pursuant to the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). These products may be exported if they meet the specifications of section 801(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

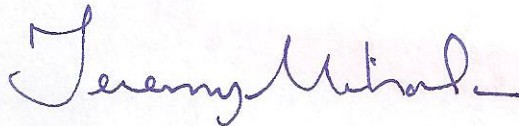
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The FDA does not approve or sanction any product or any manufacturer or distributor of such product. The Food Additives Amendment to the FD&C Act requires that we identify, in terms of chemical nomenclature, those food additives which may be safely used and the conditions under which the use of those food additives has been shown to be safe. It is the responsibility of the manufacturer or distributor to market a safe and properly labeled product (i.e., one that is safe within the meaning of the FD&C Act and the regulations promulgated under the authority of the FD&C Act, as applicable).

We can state that these products are under the jurisdiction of FDA, which has primary responsibility for the administration and enforcement of the FD&C Act. While we have not reviewed the labeling or examined the specific products that are to be offered for export, we can state that such products are eligible for export. A food additive, which is deemed a food within the meaning of section 201(f)(3) of the FD&C Act, may be exported if it complies with the FD&C Act or meets the specifications of section 801(e) of the FD&C Act (21 U.S.C. 381(e)). In accordance with the provisions of this section, a food additive intended for export shall not be deemed to be adulterated or misbranded under the FD&C Act if it:

- (a) accords to the specifications of the foreign purchaser,
- (b) is not in conflict with the laws of the country to which it is intended for export,
- (c) is labeled on the outside of the shipping package that it is intended for export, and
- (d) is not sold or offered for sale in domestic commerce.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Jeremy Mihalov", with a stylized flourish at the end.

Jeremy Mihalov
Division of Biotechnology & GRAS Notice
Review, HFS-255
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition