



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB - 5 1999

5 3 0 4 '99 FEB 23 P 1 :48

Mr. Boyd O'Donnell
International Bio-Tech USA, Inc.
1145 Linda Vista Drive
Suite 109
San Marcos, California 92069

Dear Mr. O'Donnell:

This is in response to your letter of January 28, 1999 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 International Bio-Tech USA, Inc. is making the following statement, among others, for the product Latero-Flora (Flora-Balance):

“Candida, other yeast problems, and the use of antibiotics and chemotherapy can weaken intestinal flora balance.”

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 statements that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure diseases, namely, digestive disorders caused by Candida and other pathogenic yeasts and gastrointestinal disorders associated with the use of antibiotics and chemotherapy. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (SBenz)
HFV-232 (ABrown)
GCF-1 (Dorsey)
f/t:HFS-456:rjm:2/4/99:docname:63472.adv:disc35

INTERNATIONAL

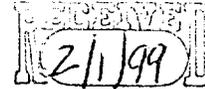
INTERNATIONAL
BIO-TECH
U.S.A., INC.

63472

BIO-TECH U.S.A.

1145 Linda Vista Drive, Suite 109, San Marcos, CA 92069 ♦ ⁷¹⁰ 619-471-1182 ♦ ⁷¹⁰ FAX 619-471-1878

Office of Special Nutritionals
(HFS-450)
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204



Dear Office of Special Nutritionals:

Notice pursuant to 403 ® (6).

International Bio-Tech makes the following notification:

1. Name and Address of Distributor:

International Bio-Tech
1145 Linda Vista Drive, Suite 109
San Marcos, CA 92069

2. Text of Statement Being Made:

Helps maintain the proper balance of intestinal flora. Candida, other yeast problems, and the use of antibiotics and chemotherapy can weaken intestinal flora balance.

3. Name of Dietary Ingredient:

Bacillus laterosporus

4. Name of Dietary Supplement:

Latero-Flora (Flora-Balance)

I, Boyd O'Donnell, certify that the information contained in this notice is complete and accurate, and International Bio-Tech has substantiation that the statement is truthful and not misleading.

Dated:

January 28, 1999

By:

Boyd O'Donnell
Boyd O'Donnell