



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG - 5 2004.

Mr. Emil Chiaberi
Chief Executive Officer
Spirit Sciences USA, Inc.
6733 S. Sepulveda Boulevard
Suite 108
Los Angeles, California 90045

Dear Mr. Chiaberi:

This is in response to your letter of July 9, 2004 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 concerned the product RU-21[®].

In your letter, pursuant to 21 CFR § 20.61, you requested that Spirit Sciences receive written notification prior to public release of your notification. Your letter did not specify the information in your notification that you believe is exempt from disclosure under exemption 4 of the Freedom of Information Act (see 21 CFR § 20.61(d)). In accordance with 21 CFR § 20.61(e)(1), this letter is to notify you that FDA has decided to disclose your submission publicly by placement of it in public docket 97S-0162. The agency, after reviewing the information in your notification, has concluded that the information contained in the notification does not appear to be confidential in that it is readily available on multiple internet web sites, including your own.

In accordance with 21 CFR § 20.61(e)(3), we intend to make this information public 5 working days after your receipt of this letter unless a U.S. District Court orders the agency not to release them.

97S-0163

LET 769

Page 2 - Mr. Emil Chiaberi

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

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

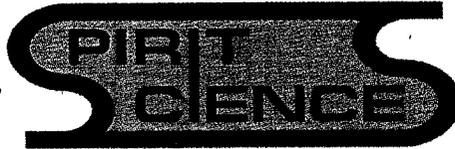
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

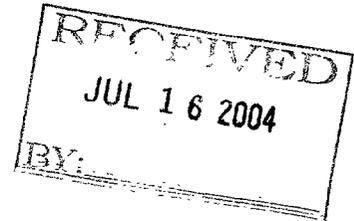
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



SPIRIT SCIENCES USA, INC
6733 S. Sepulveda Blvd., Suite 108,
Los Angeles, CA 90045
TEL: (310) 568-1030 FAX: (310) 861-5612
www.spirit-sciences.com

July 9, 2004



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-800)
Room No. 4D042
Center for Food Safety and Applied Nutrition
Food And Drug Administration
200 C Street SW
Washington, DC 20204

Reference: *Dietary Supplement Notification Pursuant to 21 C.F.R. § 101.93*
Product: *RU-21*
FDA Registration #: *17007788334*

Dear Dr. Walker:

This notification is being submitted in triplicate on behalf of Spirit Sciences USA, Inc., who is the distributor of the product which bears the statements identified in this notification.

Pursuant to 21 Code of Federal Regulations Section 101.93, Spirit Sciences USA, Inc., hereby notifies the Food and Drug Administration that they intend to market RU-21, a dietary supplement product, with labeling bearing statements provided for in 21 U.S.C. § 343(r)(6), section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

PRODUCT NAME: Spirit Sciences USA, Inc.'s "RU-21[®]"

DISTRIBUTED BY: Spirit Sciences USA, Inc.
6733 S. Sepulveda Blvd., Suite 108
Los Angeles, CA 90045

MANUFACTURED BY: AMK Market
Dnepropetrovskaya 3/5

Confidential Under 21 C.F.R § 20.61

Spirit Sciences requests written notification prior to public release of this document.

Moscow, Moskva 113587
RUSSIAN FEDERATION

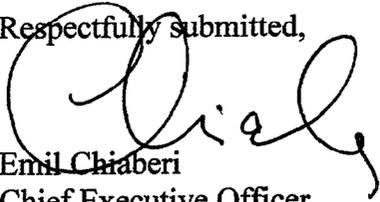
DIETARY INGREDIENTS: succinic acid,
 fumaric acid,
 L-glutamine,
 vitamin C, and
 glucose (dextrose)

STATEMENTS OF
NUTRITIONAL SUPPORT: *Promotes morning energy
 *Supports health and vitality
 *Supports the body's natural ability to metabolize alcohol

I, Emil Chiaberi, am authorized to certify this notification on behalf of Spirit Sciences USA, Inc. I certify that the information presented and contained in this notification is complete and accurate and that Spirit Sciences USA, Inc. has substantiation that each statement of nutritional support is truthful and not misleading.

Please review the above information and submit this notification to the Spirit Sciences USA, Inc. file. Should you have any questions or concerns, please contact me at (310) 568-1030 x202.

Respectfully submitted,



Emil Chiaberi
Chief Executive Officer
Spirit Sciences USA, Inc.