



The FD&C Act also provides that a dietary supplement does not include:

- an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act, or
- is an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food.

Under the FD&C Act, certain types of claims about the uses of dietary supplements may be made in labeling. Section 403(r)(6) of the FD&C Act [21 U.S.C. 343(r)(6)], added by DSHEA, allows dietary supplement labeling to bear, among other types of statements, a statement that “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans” or that “characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.” Such statements are generally referred to as “structure/function claims.” Because many of these claims would previously have been covered by the drug definition in section 201(g)(1)(C) of the FD&C Act, section 201(g)(1) was amended by DSHEA to provide that a dietary supplement “for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.” Although a dietary supplement manufacturer who wishes to make a statement permitted under section 403(r)(6) of the FD&C Act need not obtain prior review of the statement, the manufacturer must possess substantiation that the statement is truthful and not misleading, and must include in the statement the following disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” DSHEA also requires the manufacturer of a dietary supplement bearing a statement under section 403(r)(6) of the FD&C Act to notify FDA, no later than 30 days after the first marketing of the dietary supplement with the statement, that such a statement is being made for the product.

DSHEA did not alter the statutory treatment of dietary supplement claims related to disease (“disease claims”). Section 403(r)(6) of the FD&C Act, specifically provides that statements permitted under that section “may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases,” except that such statements may claim a benefit related to a classical nutrient deficiency disease, provided that they also disclose the prevalence of the disease in the United States. Consistent with the quoted provision, Congress did not modify section 201(g)(1)(B) of the FD&C Act to exclude disease claims for dietary supplements from use as evidence of intended use as a drug, as it had done for section 201(g)(1)(C) of the FD&C Act. Thus, dietary supplements “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” remain within the definition of a “drug.”

Although FDA believes that dietary supplements have potential benefits for consumers, dietary supplements labeled with unproven disease claims, i.e., those that have not met the requirements for health claim authorization or new drug approval, can pose serious risks. Such claims may encourage consumers to self-treat for a serious disease without benefit of a medical diagnosis or treatment. They may also cause consumers to substitute potentially ineffective products for proven ones, foregoing or delaying effective treatment for serious and life-threatening illnesses. Reliance on disease prevention claims may encourage consumers to feel sufficiently protected from developing serious diseases (e.g., cancer or human immunodeficiency virus (HIV) infection) that they delay or forego regular screening, and forfeit the opportunity for early medical treatment that may be critical to survival. Finally, use of dietary supplements to treat disease may increase the risk of adverse reactions due to the interaction of the dietary supplement with other compounds a consumer is taking for that disease or for other conditions, e.g., prescription medications.

Thus, there are clear and compelling public health reasons for FDA to vigorously enforce the requirements of the FD&C Act that require a product promoted to treat, prevent, or cure serious diseases to be shown to be safe and effective for its intended uses prior to its being marketed. Moreover, Congress' intent that dietary supplements should not be promoted for such uses without a showing of substantial evidence of safety and effectiveness is also clear in that it did not, in passing DSHEA, choose to exempt dietary supplements from these requirements. For these reasons, the agency is committed to enforcement of the FD&C Act to ensure that products that are properly subject to regulation as drugs are not marketed as dietary supplements. However, this does not mean that we intend to limit the availability of dietary supplements that are safe and contain ingredients that are defined as lawful dietary ingredients by the FD&C Act.

Therefore, your product, if intended for use in patients with HIV/AIDS to improve immune cell development and to extend the lives of HIV/AIDS patients and improve their quality of life, that is for the treatment or mitigation of HIV/AIDS, would be subject to regulation as a drug. If you have information to establish that it is safe and effective for its intended use, or intend to conduct clinical studies of your product as a therapeutic agent for HIV/AIDS, you may wish to submit that information to FDA in the form of a New Drug Application for review by FDA or to contact FDA's Center for Drug Evaluation and Research for more information on how to go about gaining approval of your product as a drug. Information for potential sponsors of new therapeutics for the treatment of HIV can be found at <http://www.fda.gov/cder/ode4/preind/default.htm>.

Page 4 - Mr. A. T. Scott

Please contact us if we may be of further assistance.

Sincerely yours,

Robert J. Moore  
Team Leader, Compliance and Enforcement  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

cc:

HFA-224

HF-40 (Kmalone; No. 04-2572)

HFS-22 (CCO; No. 88265)

HFS-810

f/t:HFS-810:RMoore:5/11/04:docname:88265.adv:disc84

**Owens, Shirelle**

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**From:** Owens, Shirelle  
**Sent:** Friday, May 07, 2004 10:00 AM  
**To:** Owens, Shirelle  
**Subject:** BFDRMS REPORT SENT TO EMAIL

1PROJECT: 88265 CFSAN EXECUTIVE CORRESPONDENCE OFFICE: ONPLDS  
OL/EXEC SEC NUM: 04 2572 LEVEL:

DATE OF DOCUMENT: 2004/01/19 DATE RECEIVED: 2004/05/06 DATE DUE: **MAY 4 10 51 2004**  
DATE DONE:

FROM: A.T. SCOTT, NUTRITIONAL SUPPLEMENTS CORPORATION, INC., FDA  
TRAC. NO. 04 2572

SUBJECT: SWIFT D/R-OFFERS SAMPLE OF NUTRITIONAL SUPPLEMENT CALLED  
VIADEVITA FOR HELPING TO COMBAT HIV/AIDS.

ACTION: (X) PREPARE DIRECT REPLY

INSTRUCTIONS: PLEASE RESPOND DIRECTLY, AND CLOSE OUT OF CTS UPON COMPLETION.  
FORWARD A COPY OF YOUR RESPONSE TO HFS-22CCO S. OWENS/R. WHEELER  
& K. MALONE, HF-40.

COMMENTS: COPY TO: EOS PENDING FILE

SENT TO	SENT FROM	DATE SENT	ASSIGNED
HFS-800	HFS-22CCO	05/06/2004	
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**ROUTING SLIP  
GENERATED BY: HF-40  
DATE: MAY 06,2004**

**FDA CONTROL NUMBER: 04 2572**

**TRACER#: OS #: 0121~40042**

**DATE: OF CORRESPONDENCE: 01/19/04**

**DATE INTO FDA: 05/05/04**

**T O TOMMY G THOMPSON, SECRETARY, HEALTH AND HUMAN SERVICES**

**FROM: A.T. SCOTT, NUTRITIONAL SUPPLEMENTS CORPORATION, INC.**

**SYNOPSIS: SWIFT D/R-OFFERS SAMPLE OF NUTRITIONAL SUPPLEMENT CALL D  
VIADEVITA FOR HELPING TO COMBAT HIV/AIDS. E**

**LEAD OFFICE: HFS-1**

**HOME OFFICE: HF-40**

**CONTACT/PHONE#: SHAWNEE JACOBS 301-827-4442**

**COPIES: HF-40 INDYA G MUNGO  
HFM-I**

**COORDINATION:**

**SIGNATURE REQUIRED:**

**REFERRALS FROM HF-40**

<b>ASSIGNED TO</b>	<b>ACTION</b>	<b>DUE DATE</b>
HFS-I	PREPARE DIRECT REPLY	05/18/04
REMARKS: PLEASE SEND A COPY OF RESPONSE TO KELLY MALONE, AT HF-40. THANK YOU.		



\*\*\* RECEIVED \*\*\*  
Jan 21, 2004 14:18:41 WSE 06  
OFFICE OF THE SECRETARY  
CORRESPONDENCE  
CONTROL CENTER

# ENCLOSURES

WERE NOT SCANNED

ENCLOSURE TYPE: (2) Bottles of Vitamins  
2004 01/21 14:18:41 06

PACKET TO BE  
DELIVERED MANUALLY



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

FEB 23 2004

Ms. Tina Cheatham  
Office of Executive Secretariat  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Ms. Cheatham:

Enclosed is a letter that has been forwarded from Secretary Thompson to the Centers for Disease Control and Prevention (CDC) from Nutritional Supplements Corporation, Inc.

The subject of the correspondent's request does not fall within the purview of CDC. Therefore, I am referring this letter to the Health Resources and Services Administration, which may be able to address the issue more appropriately.

Thank you for your assistance in this matter.

Sincerely,

  
Gaylon D. Morris, M.P. Aff.  
Acting Director  
Executive Secretariat

Enclosure

NOTE: Referenced vitamins not included with package. (cc)



\*\*\* RECEIVED \*\*\*  
Jan 21, 2004 14:18:41 WSP 06  
OFFICE OF THE SECRETARY  
CORRESPONDENCE  
CONTROL CENTER

RECEIVED  
04 JAN 21 PM 1:50  
NSCi  
Nutritional Supplements  
Corporation, Inc.

OFFICE OF THE SECRETARY  
COMMUNICATIONS  
CONTROL CENTER

19 January 2004

Secretary Tommy Thompson,  
U S Department of Health and Human Resources  
200 Independence Avenue S W  
Washington, D C 20201

Dear Secretary Thompson,

I am writing to provide you information on a new nutritional supplement called Viadevita, developed and patented by several physicians connected with the University of Alabama, Birmingham specifically for HIV/AIDS patients.. When you were in Birmingham last week you were quoted in the Birmingham News as saying "you have to fight it (HIV/AIDS) on all fronts". Given that premise, then I hope you will consider somehow promoting the concept of making widespread use of this "over the counter" product for HIV/AIDS patients. By vastly improving their immune cell development Viadevita has been shown to:

1. Extend the lives of HIV/AIDS patients, and
2. Improve their quality of life with increased energy, vitality, and overall wellness

It's new to the market place and not yet widely known. But it needs to be, for it can play a key role in the overall battle against AIDS.

For your information and use I have enclosed two bottles of Viadevita, and two bulletins describing it. Please see our web site at [www.viadevita.com](http://www.viadevita.com) for more detailed information. Viadevita is available now and I urge your favorable consideration of some role for it.

Please contact me as to how I might cooperate with your department.

Very truly yours,



A T Scott

PO Box 36945  
Birmingham, AL 35236

Fax: 1-205-995-0671  
[www.NutritionalSupplementsCorp.com](http://www.NutritionalSupplementsCorp.com)

1-205-936-3423  
1-800-504-1161