



Memorandum

Date APR 15 1997

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From Acting Director, Division of Programs and Enforcement Policy, Office of Special
Nutritionals, HFS-455

Subject 75-Day Premarket Notification for New Dietary Ingredients

To Dockets Management Branch, HFS-305

New Dietary Ingredient:	ReaL Build (nucleotide)
Firm:	Natural Source International, Ltd.
Date Received by FDA:	March 10, 1997
90-Day Date:	June 8, 1997

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after June 8, 1997.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and
Applied Nutrition

Attachment

cc:
HFS-22, CCO
HFS-450 (r/f, OSN w/control slip:TRAC#51509 & cpy incoming)
HFS-456 (r/f, Latham, Moore)
r/d:HFS-456:JELatham;jel:04/01/97:DocName:#51509.OSN:Disc3

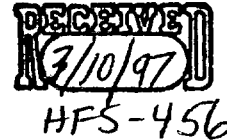
95S-0316

RPT 9

NATURAL SOURCE INTERNATIONAL, Ltd.

208 East 51st Street, Suite 331
New York, NY 10022

Tel : (212) 752-6700
Fax : (212) 319-7584



March 4, 1997

Director of Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety & Applied Nutrition
HFS-455
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Attention: Ms. Peggy Binzer

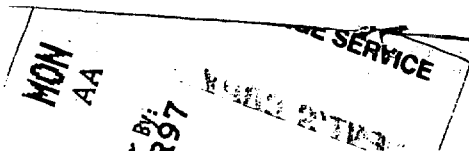
Re: Notification to the Secretary of Health and Human Services pursuant to Section 8(a)(2) of the Dietary Supplement Health and Education Act of October 25, 1994 (21 USC: Federal Food, Drug and Cosmetic Act)

Dear Ms. Binzer:

NATURAL SOURCE INTERNATIONAL, Ltd. ("NATURAL SOURCE") is a corporation incorporated pursuant to the laws of the State of New York. The purposes of **NATURAL SOURCE** are to research, manufacture and distribute organic health care products.

We herein present to you information regarding a dietary nucleotide product that we intend to market as a Dietary Supplement in the United States under the name of "Real Build".

The interest of providing a nucleotide-supplemented diet has already been disclosed in various publications. One of the most recent (Grimble, "Why are dietary nucleotides essential nutrients?", British Journal of Nutrition, [1996] - 76, 475-478) especially outlines the interest of a nucleotide -supplemented diet for patients who have undergone upper intestinal surgery.



"ReaL Build" is a specific nucleotide (RNA fragments) of great purity, developed from fermenting agents (*Escherichia Coli*) naturally present in a mammal's intestine. We feel it can improve, in an interesting manner, the nutritional value of one's daily diet especially when the body shows signs of fatigue or of a lowering level of the immune system.

ReaL Build is a safe product (its level of toxicity has been tested under the Code name "RLB") as shown by the toxicology study ("Information File") performed by SIR International, a French research institute, a copy of the conclusions of which is enclosed herein for your review.

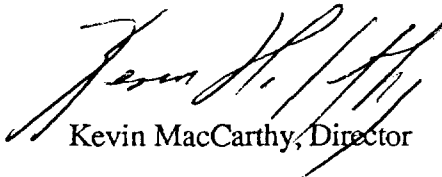
We forward to you herewith the Information File in order to provide your office with documentation evidencing the fact that "ReaL Build" is safe for human consumption.

It is our understanding that upon the expiration of seventy six (76) days following your office's receipt of this notification and, absent any responsive commentary from your office, **NATURAL SOURCE** will be able to market "ReaL Build" in the United States. Please note that we do not intend to make any medical claim to support the advertisement of this product.

Upon receipt of this letter we would appreciate it if you could forward to the undersigned an acknowledgment of same.

Should you have any questions or comments regarding the enclosed "ReaL Build" Information File, please do not hesitate to contact us.

Very truly yours,



Kevin MacCarthy, Director

Encls.

LABELING INFORMATION

Please note that we do not intend to make any medical claim to support the advertisement of this product.

We intend to package the product in small packets of 20mg each, wrapped in transparent ten packet boxes.

On each packet the following information would appear :

DIETARY SUPPLEMENT

ReaL Build

Best Before End ____

Store in cool, dry place
Keep out of reach of children
Directions: Allow to dissolve under the tongue

Lot n°

Supplement Facts

Serving size: 1 packet (20mg)
Serving per container: 10

NATURAL INGREDIENT:
Ribonucleic extract of Escherichia Coli
(Daily Value not established)

SOURCE:
Biological Cultures

Made in U.S.A.
by
Natural Source International, Ltd
208 East 51st Street
Suite 331
New York, N.Y. 10022

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