

National Organization for Rare Disorders, Inc.[®]

NORD • 100 Rt. 37, P.O. Box 8923 • New Fairfield, CT 06812-8923

(203) 746-6518 • FAX : (203) 746-6481

http://www.rarediseases.org • e-mail: orphan@rarediseases.org



... out of the darkness.
into the light ...

MEMBER ORGANIZATIONS

Alliance of Genetic Support Groups
Alpha 1 Antitrypsin Deficiency National Association
ALS Association
American Brain Tumor Association
American Laryngeal Papilloma Foundation
American Porphyria Foundation
American Society of Adults with Pseudo-obstruction, Inc. (ASAP)
American Syringomyelia Alliance Project
Aplastic Anemia Foundation of America
Association for Glycogen Storage Disease
Batten Disease Support & Research Association
Benign Essential Blepharospasm Research Foundation, Inc.
Charcot-Marie-Tooth Association
Chromosome 18 Registry and Research Society
Cleft Palate Foundation
Cornelia de Lange Syndrome Foundation, Inc.
Cystinosis Foundation, Inc.
Dysautonomia Foundation, Inc.
Dystonia Medical Research Foundation
Dystrophic Epidermolysis Bullosa Research Association (D.E.B.R.A.)
Ehlers-Danlos National Foundation
Epilepsy Foundation of America
Families of Spinal Muscular Atrophy
Foundation Fighting Blindness
Foundation for Ichthyosis & Related Skin Types (F.I.R.S.T.)
Guillain-Barre Syndrome Foundation International
HHT Foundation International, Inc.
Hemochromatosis Foundation, Inc.
Hereditary Disease Foundation
Histiocytosis Association of America
Human Growth Foundation
Huntington's Disease Society of America, Inc.
Immune Deficiency Foundation
International Fibrodysplasia Ossificans Progressiva (FOP) Association, Inc.
International Joseph Diseases Foundation, Inc.
International Rett Syndrome Association
Interstitial Cystitis Association of America, Inc.
Lowe's Syndrome Association
Malignant Hyperthermia Association of the United States
Mastocytosis Society
Myasthenia Gravis Foundation
Myeloproliferative Disease Center
Myositis Association of America
Mucopolidiosis Type IV Foundation (ML4)
Narcolepsy Network, Inc.
National Adrenal Diseases Foundation
National Alopecia Areata Foundation
National Ataxia Foundation
National Chronic Fatigue Syndrome and Fibromyalgia Association
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Marfan Foundation
National Mucopolysaccharidoses Society, Inc.
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National PKU News
National Sjogren's Syndrome Association
National Spasmodic Torticollis Association
National Tay-Sachs & Allied Diseases Association, Inc.
National Tuberos Sclerosis Association, Inc.
National Urea Cycle Disorders Foundation
Neurofibromatosis, Inc.
Obsessive Compulsive Foundation
Osteogenesis Imperfecta Foundation
Parkinson's Disease Foundation, Inc.
Prader-Willi Syndrome Association
Pulmonary Hypertension Association
PXE International, Inc.
Reflex Sympathetic Dystrophy Syndrome Association
Scleroderma Foundation, Inc.
Sickle Cell Disease Association of America, Inc.
Tourette Syndrome Association, Inc.
Trigeminal Neuralgia Association
United Leukodystrophy Foundation, Inc.
United Mitochondrial Disease Foundation
VHL Family Alliance
Wegener's Granulomatosis Support Group, Inc.
Williams Syndrome Association
Wilson's Disease Association

May 28, 1999

4250 '99 JUN 21 A10:19

Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-1174
Dietary Supplements
Center for Food Safety and
Applied Nutrition Strategy

Dear Sirs:

In response to the Federal Register notice soliciting comments that will assist CFSAN to develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA), the National Organization for Rare Disorders (NORD) wishes to submit the following comments:

NORD is a consumer federation of approximately 140 voluntary health agencies and thousands of individuals dedicated to the identification, treatment, and cure of rare "orphan diseases." Some people with rare disorders have valid medical need for products that are not available for sale as pharmaceuticals, but are only available as nutritional supplements. Because nutritional supplements are unregulated, we are very concerned about the lack of quality of these products and the absence of uniform standards promising that every pill or tablet must contain the exact amount of active ingredients specified on the label.

One hundred years ago patent medicines sold in the United States claimed to cure every malady known to man from arthritis to cancer, syphilis, liver and kidney diseases, tuberculosis, etc. It was only after several public health crises and needless deaths from unregulated medicines that the United States government required proof of safety before medications could be marketed. During the 1960's, the law was changed to also require proof of efficacy. Today, as the century comes to a close, this nation has reverted one hundred years to an era of unregulated medicines that are advertised as effective against health problems without any scientific proof, and without any assurance of safety. As a consequence of DSHEA, consumers have become convinced that "natural" food supplements are safe. FDA is taking action only after the public health consequences of unregulated products maim or kill people who were given no warning about unsafe and dangerous nutritional supplements.

99N-1174

C19

Associate Members

Acid Maltase Deficiency Association
Aicardi Syndrome Newsletter, Inc.
ALS Association/Greater Philadelphia Chapter
American Autoimmune Related Diseases Association
American Bechet's Disease Association, Inc.
American Pseudo-obstruction & Hirschsprung's Disease Society, Inc.
American Self-Help Clearinghouse
Androgen Insensitivity Group
Angel View Grippled Children's Foundation

A-T Project
Ataxia Telangiectasia Children's Project
CDGS Family Network
Canadian Organization for Rare Disorders
Children's Hospital Medical Center, Akron Ohio
Children's Leukemia Foundation/Michigan Children's Medical Library
Children's PKU Network
Chromosome Deletion Outreach, Inc.
Chronic Granulomatous Disease Association, Inc.
Consortium of Multiple Sclerosis Centers
Contact A Family

Cooley's Anemia Foundation
Cushing Support & Research Foundation
Earl Goldberg Aplastic Anemia Fountain
Family Caregiver Alliance
Family Support System for North Carolina
Freeman-Sheldon Parent Support Group
Hydrocephalus Association
International Foundation for Alternating Hemiplegia of Childhood
JUMP Foundation
Klippel-Trenaunay Support Group
Late Onset Tay-Sachs Foundation
Les Turner ALS Foundation, Inc.

National Association for Pseudoexanthoma Elasticum
National Coalition for Research in Neurological & Communicative Disorders
National Gaucher Foundation
National Incontinentia Pigment Foundation
National Niemann-Pick Disease Foundation
National Oral Health Information
National Patient Air Transport Hotline
National Spasmodic Dysphonia Association
Neutropenia Support Association
Organic Acids Association
Osteoporosis and Related Bone Diseases

National Resource Center
Parents Available to Help (PATH)
Parent to Parent of Georgia, Inc.
Parent to Parent of New Zealand
Recurrent Respiratory Papillomatosis Foundation
Research Trust for Metabolic Diseases in Children/United Kingdom
Restless Legs Syndrome Foundation
Sarcoid Networking Association
Shwachman Syndrome Support Group
Sichel Cell Disease Association of Texas
Gulf Coast Society For Supranuclear Palsy, Inc.

Solos Syndrome Support Association
Sturge-Weber Foundation
Treacher Collins Foundation
Vaincre les Maladies Lyssosomales/France

* Associations are joining continuously. For newest listing, please contact the NORD office.

Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
May 28, 1999
Page Two

The FDA has not moved fast enough to remove dangerous nutritional supplements from the market, and supplement manufacturers do not hesitate to market products with known public health risks. Even after the agency calls for withdrawal of unsafe supplements, retail stores continue to sell them. We urge the FDA to increase enforcement actions to prevent further public health tragedies, and to require manufacturers to test these products before they are sold to an unwitting public.

The following will address specific questions noted in the federal notice:

1. In addition to assuring consumers access to safe dietary supplements that are truthfully labeled, FDA should assure that the products are bioequivalent, meet uniform dissolution standards, and are labeled for contraindications, side effects, etc.

FDA should require manufacturers conformance to Good Manufacturing Practices (GMPs), and assure that the ingredient labeling on a supplement bottle indicates the exact content of each tablet or capsule. 100 mg. of Vitamin C should contain 100 mg. no matter which brand a consumer buys. There is no other group of consumer products that is allowed to be sold in the United States unregulated. Many tests have shown that supplements often do not contain the exact ingredients claimed on the label, some supplements are sub-potent, some are super-potent, and some contain no active ingredients at all. Even pills within the same bottle can vary as to contents. This is a "buyer-beware" market because of the absence of government regulation. FDA's inability to test the contents of supplements has put the public at the mercy of dishonest vendors. There are people with rare diseases who have valid medical need for supplements, but they cannot rely on the quality of these products without government regulation.

We suggest that nutritional supplement companies should conform to the same quality regulations as generic drugs and over-the-counter pharmaceuticals. They should be required to submit proof of bioequivalence and dissolution testing. Bottles of supplements should be required to post an expiration date and side effect warnings meeting the same standards as over-the-counter drugs.

Many consumers are not aware that supplements may have side effects, that they should not be taken with other drugs or foods, and as a consequence there have been many critical and even life-threatening events arising out of use of some of these products. Without adequate warnings, the public is not provided reasonable information upon which to base their decisions. When FDA issues press releases to inform the public about serious side effects or supplement interactions, the agency's outreach efforts are inadequate. Warnings should be posted on product containers, not a ten-second announcement on the nightly news.

Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
May 28, 1999
Page Three

2. We advise FDA, because its primary mission is a consumer protection agency, that safety should be the highest priority in your supplement strategy. For example, despite documented reports that the supplement 5HTP contained the same flawed tryptophan that killed or maimed several thousand Americans a few years ago, 5HTP continues to be sold over-the-counter as a nutritional supplement. FDA "asks" for "voluntary" recalls of dangerous products whereas it should require recalls of products with evidence of imminent public health hazards. Such products should be ordered off the market without delay. FDA should aggressively express its need to Congress for more statutory authority to withdraw dangerous supplements before people are harmed, not after. It is incredible that more than 800 adverse events were reported from ephedra before FDA took action. Similarly, a "voluntary" recall of GHB and related products represents insufficient protection of public health by the agency. If the government can recall thousands of cars because of an automobile defect, it is incredulous that FDA cannot recall nutritional supplements that have caused critical health problems and deaths.
5. There are many other safety, labeling, and marketplace issues that FDA should address without further delay. There are too many supplements labeled "USP," which is supposed to indicate that they conform to the U.S. Pharmacopoeia standards, but they do not in fact live up to those standards. Apparently USP is aware of the violations, but it is not a government agency and has no enforcement authority. FDA does have enforcement authority against untruthful labeling, and it should do something to stop this dishonest practice by violative supplement companies.

Similarly, FDA should issue GMP regulations for nutritional supplements; require expiration dates on all bottles; require manufacturers proof of testing for dissolution and bioequivalence; list warnings and side effects clearly on all labels; and require a stronger statement on labels that each product has not been tested for safety nor effectiveness and is not approved by the FDA. The public is under the impression that FDA will not allow any unsafe or ineffective product to be sold; therefore they believe that nutritional supplements are approved by the agency for sale in the United States.

Consumers should know by reading the labels on nutritional supplements that they are taking personal responsibility for ingesting untested and unproven products that may or may not have health implications, both good or bad. They should be able to read understandable warnings about known side effects, just like they read on an aspirin bottle. They should learn via the label whether to take the supplement with or without food and which medications they should avoid. FDA should vigorously monitor and regulate the outrageous print and television advertisements that are misleading and untruthful. By allowing these ads to continue, FDA has allowed the snake oil salesmen of the beginning of this century to roll back the consumer protection clock by 100 years.

Very truly yours,



Abbey S. Meyers
President

ASM:aa

cc: Elizabeth Yetley, Ph.D.
Director, Office of Special Nutritionals
Center for Food Safety and Applied Nutrition



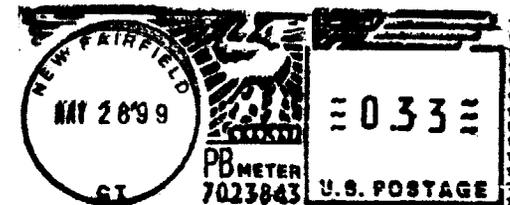
out of the darkness
into the light®

FORWARDING AND RETURN
POSTAGE GUARANTEED
ADDRESS CORRECTION
REQUESTED

National Organization for Rare Disorders, Inc.®

NORD • P.O. BOX 8923 • New Fairfield, CT 06812-8923

CFC# 0551



HFS-450
Jm
ELIZABETH A YETLEY PHD
DIRECTOR, OFFICE OF SPECIAL
NUTRITIONALS
CENTER FOR FOOD SAFETY AND APPLIED
NUTRITION
DEPARTMENT OF HEALTH & HUMAN