

National Organization for Rare Disorders, Inc.®



Out of the darkness
into the light

NATIONAL MEMBER ORGANIZATIONS

Alagille Syndrome Alliance
Alpha 1 Association
Alpha 1 Foundation
American Brain Tumor Association
American Laryngeal Papilloma Foundation
American Porphyria Foundation
American Synngomyelia Alliance Project
Amyotrophic Lateral Sclerosis Association (ALS)
Aplastic Anemia & MDS International Foundation, Inc.
Association for Glycogen Storage Disease
Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
Batten Disease Support & Research Association
Benign Essential Blepharospasm Research Foundation
Charcot-Marie Tooth Association
Chromosome 18 Registry Research Society
Cleft Palate Foundation
Comecia De Lange Syndrome Foundation
Cystinosis Foundation, Inc.
DEBRA of America
Dysautonomia Foundation, Inc.
Dystonia Medical Research Foundation
Ehlers Danlos National Foundation
Epilepsy Foundation
Families of Spinal Muscular Atrophy
Foundation for Ichthyosis and Related Skin Types
Genetic Alliance
Guillain Barre Syndrome Foundation International
Hemochromatosis Foundation
Hereditary Colon Cancer Association
Hereditary Disease Foundation
HHT Foundation International, Inc.
Histiocytosis Association of America
Huntington's Disease Society of America
Immune Deficiency Foundation
International FOP Association, Inc.
International Joseph Diseases Foundation, Inc.
International Rett Syndrome Association
Interstitial Cystitis Association
Lowe Syndrome Association, Inc.
Mastocytosis Society, Inc.
Mucopolidosis Type IV Foundation, Inc.
Myasthenia Gravis Foundation of America, Inc.
Myeloproliferative Disease Research Center
Myositis Association of America, Inc.
Narcolepsy Network, Inc.
National Adrenal Disease Foundation
National Alopecia Areata Foundation
National Ataxia Foundation
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Marfan Foundation
National MPS Society, Inc.
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National PKU News
National Spasmodic Torticolis Association
National Tay Sachs & Allied Diseases Association
National Urea Cycle Disorders Foundation
Neurofibromatosis, Inc.
Osteogenesis Imperfecta Foundation
Parkinson's Disease Foundation, Inc.
Platelet Disorder Support Association
Prader Willi Syndrome Association, USA
Pulmonary Hypertension Association
PXE International, Inc.
Reflex Sympathetic Dystrophy Syndrome Association
Scleroderma Foundation
Sickle Cell Disease Association of America
Stevens Johnson Syndrome Foundation
Sturge-Weber Foundation
The Erythromelalgia Association
The Oxalosis and Hyperoxaluria Foundation
The Pagel Foundation
Tourette Syndrome Association
Trigeminal Neuralgia Association
United Leukodystrophy Foundation
United Mitochondrial Disease Foundation
VHL Family Alliance
Wegener's Granulomatosis Association
Williams Syndrome Association
Wilson's Disease Association

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March 10, 2003

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

Re: Docket No. 95N-0304
Dietary Supplements Containing
Ephedrine Alkaloids

Dear Sirs or Madams:

We welcome FDA's reopening of the comment period for the June 4, 1997 *Federal Register* notice regarding ephedrine alkaloids. That notice proposed a warning statement on the labels of these dietary supplements, and restriction on the potency and composition of ephedrine alkaloid products. The notice was published six years ago, and we deeply regret the loss of life and permanent disability that thousands of consumers have experienced from these products in the interim.

There have been 17,000 adverse event reports from ephedra supplements submitted to FDA in recent years, not to mention thousands more consumers who have suffered these side effects and not reported them to the agency. Additionally, FDA is aware of two deaths, four heart attacks, nine strokes, one seizure, and five psychiatric cases where no contributing factors have been identified. The recently published article in the *Annals of Internal Medicine* indicates that although ephedra products make up less than one percent of all dietary supplement sales, these products account for 64 percent of adverse events associated with dietary supplements. This is evidence enough for FDA to regulate these products.

FDA is empowered to regulate nutritional supplements that represent a significant or unreasonable risk of injury. The time is long overdue for the agency to take action against ephedra products that are manufactured and marketed as nutritional supplements. However, we believe a warning statement may NOT be sufficient to curb the injuries that are precipitated by these unregulated products. There should also be restrictions on the potency and composition of products containing ephedrine alkaloids. In fact, because the public believes that FDA protects the public health, we would applaud action by the FDA to withdraw these products from the market.

95N-0304

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Associate Member Organizations

Acid Maltase Deficiency Association (AMDA)
Alternating Hemiplegia of Children Foundation
American Autoimmune Related Disease Association
American Behcet's Disease Association
Amyotrophic Lateral Sclerosis (ALS) of Greater Philadelphia Chapter
A-T Children's Project
(The) CDG Family Network Foundation
Canadian Organization for Rare Disorders (CORD)
Children's PKU Network

Chromosome Deletion Outreach Inc.
Chronic Granulomatous Disease Association
CLIME
Consortium of Multiple Sclerosis Centers
Contact A Family
Cooley's Anemia Foundation, Inc.
Cushing Support & Research Foundation, Inc.
Family Caregiver Alliance
Family Support Network of North Carolina
Freeman-Sheildon Parent Support Group

Hydrocephalus Association
Incontinence Pigment International Foundation
K-T Support Group
Late Onset Tay-Sachs Foundation
Les Turner ALS Foundation Ltd.
Merry Medical Airlift
National Lymphedema Network, Inc.
National Niemann Pick Disease Foundation
National Spasmodic Dysphonia Association
Organic Acidemia Association

Osteoporosis and Related Bone Diseases National Resource Center
Parent to Parent New Zealand, Inc.
Rare & Expensive Disease Management Program (REM)
Rescurrent Respiratory Papillomatosis Foundation
Restless Legs Syndrome Foundation
Saroid Networking Association
Shwachman - Diamond Syndrome International
Society for Progressive Subnuclear Palsy, Inc.

Sotos Syndrome Support Association
St. Claire's Health Services
Tawan Foundation for Rare Disorders
Takayasu's Arteritis Association

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

Rev 10/02

Dedicated to Helping People with Orphan Diseases

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Food and Drug Administration
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It is unfortunate that as evidence mounted about the dangers of ephedra products, FDA has not taken action until a well-known sports figure died as a result of this nutritional supplement. If FDA believes that it is not empowered to regulate ephedra products under the *Dietary Supplement Health and Education Act* (DSHEA), we strongly urge the agency to call for modifications to the legislation to expand the agency's powers to:

- 1) Require nutritional supplement manufacturers to prove the safety of their products BEFORE they are allowed to be marketed in the United States.
- 2) Require FDA approved labeling on all nutritional supplements, akin to labeling for all over-the-counter drugs.
- 3) Enhanced powers for the agency to order immediate withdrawals from the market of any nutritional supplement that represents an unreasonable risk to the public health.
- 4) Provisions that would give the agency authority to regulate dissolution, bioavailability, and purity of ingredients in all nutritional supplements. As you know from numerous reports, many supplements have no active ingredients, some have too much, and some have only a percentage of the labeled ingredients in each pill.

It is important to remember that people do NOT read labels on most over-the-counter drugs (no less nutritional supplements that are marketed as "natural" and "safe"), and supplements are commonly used for off-label uses that are found in health magazines (not the product packaging). Many consumers believe that "more is better", so a warning label may not enhance the safety of these products sufficiently. Because most people mistakenly believe the FDA regulates nutritional supplements they are totally unaware that there may be risk associated with any of these products, not just ephedra. Therefore, we believe that FDA should be empowered to regulate the supplement industry. If DSHEA has to be amended, we would support the FDA's effort to do so.

Very truly yours,



Abbey S. Meyers
President

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