

National Organization for Rare Disorders, Inc.®



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NATIONAL MEMBER ORGANIZATIONS

Alagille Syndrome Alliance
 Alpha 1 Association
 Alpha 1 Foundation
 American Brain Tumor Association
 American Laryngeal Papilloma Foundation
 American Porphyria Foundation
 American Syringomyelia 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-Mane Tooth Association
 Chromosome 18 Registry Research Society
 Cleft Palate Foundation
 Cornelia 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
 Histocytosis 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 Torticollis 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 Paget 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

March 11, 2003

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

Re: **Docket No. 96N-0417**
FDA Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients & Dietary Supplements

Dear Sirs or Madams:

We are very pleased that FDA has finally published proposed labeling and manufacturing standards for dietary supplements. These regulations are long overdue, and we urge you to finalize the rules as quickly as possible, and then vigorously enforce them.

As FDA knows, many dietary supplements have been adulterated or misbranded. CGMPs are needed to prevent sub-potent and super-potent products, and contaminated products that are a danger to public health. Every nutritional supplement product should be manufactured with rigorous quality controls, as well as standardized packaging and labeling. The industry's attempts to regulate itself have been a miserable failure.

We are concerned, however, that large manufacturers will have one year to comply, while small manufactures will have three years to comply. When consumers purchase a nutritional supplement, they do not have any idea if the manufacturer is small or large. Thus they may be purchasing mislabeled and adulterated products up to three years from now, while mistakenly believing that FDA regulates the product.

We suggest that any product that does not live up to these standards one year after the regulations go into effect should be labeled to say, "This product may not conform with government standards for purity and potency." This will give consumers a reasonable warning that the manufacturer has not met government standards. It will also prevent small fly-by-night manufacturers from making sham products and then going out of business within a year. Similarly it will reward small companies that comply with the new standards before the three-year limit.

96N-0417

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Associate Member Organizations

Acid Maltase Deficiency Association (AMDA)	Chromosome Deletion Outreach Inc	Hydrocephalus Association	Osteoporosis and Related Bone Diseases National Resource Center	Sotos Syndrome Support Association
Alternating Hemiplegia of Children Foundation	Chronic Granulomatous Disease Association	Incontinence Pigment International Foundation	Parent to Parent New Zealand Inc	St. Clare's Health Services
American Autoimmune Related Disease Association	CLIMB	K-T Support Group	Rare & Expensive Disease Management Program (REM)	Tawan Foundation for Rare Disorders
American Behcet's Disease Association	Consortium of Multiple Sclerosis Centers	Late Onset Tay Sachs Foundation	Recurrent Respiratory Papillomatosis Foundation	Takayasu's Arteritis Association
Amyotrophic Lateral Sclerosis (ALS) of Greater Philadelphia Chapter	Contact A Family	Les Turner ALS Foundation Ltd	Restless Legs Syndrome Foundation	
A-T Children's Project	Cooley's Anemia Foundation Inc	Mercy Medical Airlift	Sarcoid Networking Association	Associations are joining continuously For newest listing please contact the NORD office
(The) CDG Family Network Foundation	Cushing Support & Research Foundation Inc	National Lymphedema Network Inc	Shwachman - Diamond Syndrome International Society for Progressive Supranuclear Palsy Inc	
Canadian Organization for Rare Disorders (CORD)	Family Caregiver Alliance	National Niemann-Pick Disease Foundation		
Children's PKU Network	Family Support Network of North Carolina	National Spasmodic Dysphonia Association		
	Freeman-Sheidon Parent Support Group	Organic Acidemia Association		

Dedicated to Helping People with Orphan Diseases

Dockets Management Branch (HFA-305)
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We applaud the FDA for finally moving forward to protect the public from mislabeled and contaminated nutritional supplements. We urge you to finalize the regulations quickly, and then to rigorously enforce them.

Very truly yours,

A handwritten signature in black ink, appearing to read "Abbey S. Meyers". The signature is fluid and cursive, with a large initial "A" and "M".

Abbey S. Meyers
President

ASM:aa

cc: Diane E. Dorman, NORD Vice President for Public Policy