To: Dr. Barbara Schneeman
Director, Office of Nutritional Products Labeling and Dietary Supplements
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

To: Dr. Edward Scarborough
U.S. CODEX Manager - U.S. CODEX Office
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To: Receiver of Dockets
Dockets Management Branch
Department of Health and Human Services
Food and Drug Administration
Room 1061, 5630 Fishers Lane
Rockville, MD 20852

Second Amendment to
CITIZEN PETITION
for Furtherance of Dietary Supplement Harmonization Policy by the U.S. CODEX Delegation and Food and Drug Administration, in Harmony with DSHEA and 19 USC 3512

This Second Amendment is submitted with regard to the Citizen Petition of June 1, 2005, (Amended June 14, 2005) urging the US Codex Office to further, as its policy, harmonization with the CODEX Vitamin and Mineral Guideline (VMG) only in conformity with existing US Law and includes the issues raised therein by reference and to refrain from harmonization via either legislative or regulatory means with any standard, guideline or regulation which conflicts with or violates US current Law. Attached hereto and made a part hereof is a copy of the VMG, marked for amendment to conform to existing United States laws and regulations.

This Petition is further addressed to the Food and Drug Administration, as the agency responsible for US Policy on food and nutrient safety at the International Food Safety Agency, including herein, by reference the original Petition and the First Amendment thereto, copies of which are appended hereto.

Further the Petitioner states:

Factual Background

1. (a) The Vitamin and Mineral Guideline adopted by CODEX on July 4 2005 uses inappropriate science (i.e., Risk Assessment procedures [Toxicology]) rather than appropriate science (i.e., Nutritional Science [Biochemistry]) which is very likely to inappropriately mandate maximum permissible levels of nutrients so low that they are, by intention, without impact on

any human being, the intended outcome of Risk Assessment procedures; a Fact Hearing must be, and petitioner hereby requests that a fact hearing be, held to determine the scientifically factual and appropriate basis for the use of Risk Analysis [Toxicology] rather than more appropriate nutritional [Biochemistry] scientific standards in all decisions pertaining to nutrition.

(b) Codex has accepted the use of Risk Assessment procedures for nutrients. However, Risk Assessment is a methodology relevant only to toxicology and both irrelevant and antithetical to Nutritional Science and biochemistry. The Risk Assessment methodology employed by CODEX has been arbitrarily modified without scientific validation or professional consensus to restrict permissible dosages of nutrients essential to life to levels which can, by intent, have no impact on any human being, no matter how sensitive. This misapplication, distortion and misconstruction of Risk Assessment is in clear contradiction to the principles of toxicology and scientific Risk Assessment procedures which have been developed to determine the highest dosages of dangerous industrial and natural toxins to which humans can be exposed to without discernable effect. For this reason, instead of evaluating vitamin and mineral upper limits using inappropriately modified and unscientific Risk Analysis, US Policy must further the use of Nutritional Science to support the liberal access to nutrients enjoyed under legislative protection in the US. Under the Dietary Supplements Health and Education Act, passed by unanimous Congressional consent in 1994, while a nutrient may be dealt with by the FDA if it is shown to pose a significant risk to health and safety, nutrients are treated as foods which, as such, may have no upper limits set upon their use.

(c) The United States has failed to oppose the use of these scientifically unsupported and unverified Risk Assessment techniques in the CODEX Committee on Nutrition and Foods for Special Dietary Uses. It has failed to note or oppose these procedures on the basis of the substantial Conflict of Interest represented by the publicly acknowledged personal, professional and financial involvement in commercial Risk Assessment by the Chairman of the Codex Committee on Nutrition and Foods for Special Dietary Uses as the head of the BfR, a commercial Risk Assessment company. The United States has failed to oppose the classification of nutrients as toxins in 1994, by that same committee despite the clear violation of US law which that classification represents. And, since 1994, the United States has failed to present any opposition to the use of Risk Analysis and other attempts to limit access to nutrients in order to prevent the restrictive (and illegal under US law) Vitamin and Mineral Guideline from reaching Step 8 and from being ratified on July 4, 2005 at the 28th CODEX ALIMETNARIUS Commission meeting in Rome, Italy, contrary to DSHEA (Dietary Supplement health and Education Act of 1994) and the unanimous determination of Congress that Dietary Supplements are Foods, not toxic substances and, as foods, can have no upper limit set upon their intake or use.

(d) U.S. District Court Judge Tena Campbell stated in the Ephedra Decision, April 2005 (*Nutraceutical Corporation and Solaray, Inc. v. Lester Crawford, Acting Commissioner, U.S. Food and Drug Administration*, Case No. 2:04CV409 TC, USDC, Utah Central Division),

"…the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection..."

(e) The CODEX Technical Report discussing the application of Risk Assessment to nutrients makes it clear that this procedure does not apply to nutrients because, unlike drugs, they have minimum intake limits that are required for life and health. Risk Assessment procedures were modified for application to vitamin and mineral supplements without scientific validation, peer review or clinical testing. There is a considerable body of literature supporting the nutritional harm caused by low-level intake of essential and vital nutrients. Has the United States held a public fact finding hearing to determine if this jerry-rigged statistical system has any applicability to Nutritional Science and what the risks to the US and global population are when Risk Assessment is applied to nutrients? If not, why has the US supported the use of

this technique in the nutritional determinations made by the CCNFSDU when so many lives are at stake in this issue, estimated by public health scientists to exceed 3 Billion consequential deaths world-wide? Why has the US supported and adopted this scientifically, biologically and factually indefensible Policy which should be abandoned in favor of a Policy which supports and promotes nutrients as foods, as DSHEA mandates, as the domestic and international standard which are so strongly supported by both science and US Law? A fact Hearing must be, and petitioner hereby request that a fact hearing be, held to determine the impact on public health in the United States from the use of Risk Analysis [Toxicology] rather than more appropriate nutritional [Biochemistry] scientific standards.

(f) We have appended hereto, and make part hereof, the Alliance for Natural Health (ANH) and Citizens for Health (CFH) comments on the failure of toxic Risk Assessment to conform to standards of science.

Legal Authority

2. (a) The US Codex Office, the FDA and all other involved agencies have legal authority to further international harmonization only in conformity with US law:

Title 19, Section 3512, forbids the US from harmonizing with standards which violate US law;

The Dietary Supplement Health Education Act (DSHEA), 1994 classifies supplements as foods which therefore may have no Safe Upper Limits, Maximum Permissible Upper Limits or other restrictions upon their use.

(b) FDA has adopted a policy of harmonization with International Standards, even where those standards are not finalized. "In a notice published in the Federal Register of October 11, 1995 (60 FR 53078), FDA articulated its policy regarding the development and use of standards with respect to the harmonization of various national and international regulatory requirements and guidelines" - http://www.cfsan.fda.gov/~lrd/fr970707.html .

(c) The adoption of the Risk Assessment Model and the anti-DSHEA harmonization Policy are *ultra vires* and premature; have occurred without sufficient Public Hearings and in direct contravention of the Public Policy of the United States as enacted by Congress. The appropriate US agencies must therefore assert a Nutritional Standard as the only lawful alternative to the inappropriate and unscientific use of toxicological Risk Assessment with regard to Dietary Substances. It is incumbent upon the United States therefore to ensure that the proper science is presented and considered in the process of attempting to set upper limits for nutrient supplements and to vigorously support the reopening of the Vitamin and Mineral Guideline to correct its scientific deficiencies since the science upon which it is based, relying on toxicology while ignoring the appropriate science, biochemistry, is flawed, creating a position that is contrary to US legal requirements and domestic (as well as global) health and well being of every man, woman and child on the planet.

(d) The Natural Solutions Foundation, in cooperation with Citizens for Health, has caused its attorneys to prepare a Revised Version of the Vitamin and Mineral Guideline more in conformity with the requirements of Law. A copy of the Revised Version is attached hereto and made a part hereof (together with a comparison copy, showing the specific changes requested).

Environmental Statement

3. (a) Environmental Impact information is generally required only if the petition requests approval of food or color additives, drugs, biological products, animal drugs, or certain medical devices, or for a food to be categorized as GRAS (generally recognized as safe) under the Procedures for preparing environmental impact statements found in Title 21, Part 25 of the Code of Federal Regulations. An environmental impact statement is therefore not required.

Actions requested

4. The Petitioner requests the following Actions by the agencies, with regard to CODEX and the International Food Safety Agency:

(a) The opening of an appropriate Docket for this Petition and for consideration of the Revised Version of the Vitamin and Mineral Guideline.

(b) The holding of Public Hearings on following Questions of Fact:

1. Whether or not the use of Toxic Risk Assessment to determine the allowable forms and dosages of Vitamins and Minerals will promote public health. Petitioners assert it will not, as the use of Risk Assessment is inappropriate science with reference to Foods, including Vitamins and Minerals

2. Whether forms and dosages of Vitamins and Minerals determined through Toxic Risk Assessment will adversely impact on the health and well-being of the residents and Citizens of the United States.

(c) (1) The adoption of the Revised Version of the Vitamin and Mineral Guideline (attached hereinafter) to promote harmonization in conformity with United States Law, and (2) support for such harmonization at future CODEX and International Food Safety Agency meetings.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitions that are unfavorable to the petition.

Dated: October 14, 2005

Natural Solutions Foundation

Cc: George W. Bush, President
Richard B. Cheney, Vice President
Secretary of HHS
Secretary of Commerce
Secretary of Agriculture
Secretary of Transportation
Commissioner of EPA
Commissioner of FDA
Barbara Schneeman, FDA
Sen. William Frist, MD
Rep. Dennis Hastert
Sen. Harry Reid
Rep. Nancy Pelosi

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Maj. Gen. Albert N. Stubblebine III (US Army, Ret.)
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