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May 7, 2002

VIA OVERNIGHT COURIER

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 10-61
Rockville, MD 20857

CITIZEN PETITION
Regarding Lead and Cadmium Levels to be Permitted in Cocoa
Under Applicable Standards of the *Codex Alimentarius* Commission

Dear Sir or Madam:

On behalf of the American Environmental Safety Institute ("Petitioner"), I write to submit (in quadruplicate) pursuant to Section 505(j)(2)(C) of the federal Food, Drug and Cosmetic Act, and in accordance with 21 Code of Federal Regulations ("CFR") section 10.30, Petitioner's request that the Commissioner of the Food and Drug Administration instruct the delegates from the United States to seek to amend the "Draft Standard for Chocolate and Chocolate Products" pending before the *Codex Alimentarius* Commission of the World Health Organization to establish maximum permitted levels of the toxic metals lead and cadmium in cocoa and cocoa products.

A. Action Requested

Petitioner requests that the Commissioner of the Food and Drug Administration instruct the delegates from the United States to seek to amend the "Draft Standard for Chocolate and Chocolate Products," currently pending before the *Codex Alimentarius* Commission of the World Health Organization, to establish maximum permitted levels of the toxic metals lead and cadmium in cocoa and cocoa products, such that the resulting finished chocolate products sold at retail contain no more than:

- 0.02 parts-per-million of lead, and
- 0.02 parts-per-million of cadmium.

B. Statement of Grounds

Petitioner makes this request based upon the facts and law presented in the attached paper entitled "**LEAD IN CHOCOLATE: THE IMPACT ON CHILDREN'S HEALTH**," attached as Exhibit 1 to this Petition. In summary, Petitioner establishes in this paper that most of the lead and cadmium present in wholesale and retail chocolate (and related

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cocoa products) is a result of man-made sources, which can and should be reduced to preclude the known and documented adverse health effects in the children and adults who consume the lead and cadmium in these chocolate products. Petitioner also establishes that the current levels of lead and cadmium in chocolate and cocoa products pose a clear and present health danger to consumers, especially to children under 7 years of age, based upon data from the California Office of Environmental Health Assessment, the federal Centers for Disease Control, the U.S. Department of Agriculture, and the U.S. Food and Drug Administration. In that cocoa is the primary raw material in chocolate products, the United States must take a leadership role in seeking to reduce the toxic metals lead and cadmium in the cocoa and cocoa products used in making chocolate products.

C. Environmental Impact

While an environmental assessment on the action requested in this Petition qualifies for a categorical exclusion under 21 CFR section 25.31, Petitioner's attached paper demonstrates that the proposed reduction in lead and cadmium in chocolate and cocoa products will result in significant positive impacts on the environment in cocoa bean-producing countries, for their indigenous populations, as well as for the chocolate and cocoa consuming populations, all around the world.

D. Economic Impact

Pursuant to 21 CFR section 10.30(b), economic impact information is to be submitted only when requested by the Commissionr. Petitioner will promptly provide such information, beyond that already included in the attached paper, if so requested. Please make any such request to the undersigned, who is also available to answer any questions.

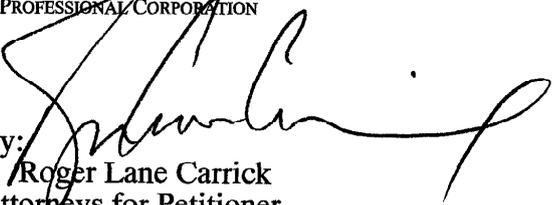
E. Certification

On behalf of Petitioner, the undersigned certifies that, to the best of my knowledge and belief, this Petition includes all information and views on which the petition relies, and that it also includes that representative data and information known to the Petitioner that may be unfavorable to the Petition.

Please direct any response or inquiry regarding this Petition to the undersigned, who is also available to answer any questions.

Respectfully submitted,

THE CARRICK LAW GROUP
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By: 
Roger Lane Carrick
Attorneys for Petitioner
American Environmental Safety Institute,

Attachment
RLC/kb