NNFA

National Nutritional Foods Association

December 21, 2000

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

Re: Foods Derived from New Plant Varieties,
Docket Number 99P-5493

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting this letter to the Food and Drug Administration ("FDA") as an addendum to its December 20, 1999 Citizen Petition regarding foods containing genetically modified organisms ("GMO foods"). "Foods Derived from New Plant Varieties," Docket Number 99P-5493.

For over sixty years, NNFA has been the trade association representing the interests of more than 1,000 suppliers and 3,000 retailers of natural foods, dietary supplements and other natural products throughout the United States. A central tenet of NNFA's mission is to assure that the integrity of the American food supply is safeguarded. The Association shares a genuine concern with millions of other interested persons about the consequences of human consumption of genetically modified foods. NNFA aims to ensure that the market entry of GMO foods does not outpace thorough scientific evaluations of their safety.

In its 1999 Citizen Petition, NNFA urged the agency to amend its "Statement of Policy: Foods Derived from New Plant Varieties," 57 Fed. Reg. 22984, May 29, 1992 ("1992 GMO Foods Policy") to ensure that GMO foods are safe. Specifically, NNFA asked that FDA mandate that GMO foods which are claimed to be generally recognized as safe ("GRAS") by their manufacturers be evaluated by FDA for safety, prior to going to market, under a procedure that provides well defined scientific risk assessment criteria and the opportunity for input by qualified, independent scientific experts.

99P-5493

AMD

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NNFA wishes to reaffirm the positions taken in the Citizen Petition and, through this letter, to supplement that petition by recommending two additional steps the agency should take to ensure the safety and traceability of GMO foods.

First, NNFA urges FDA to mandate that manufacturers of GMO foods submit a valid programmatic environmental impact statement ("EIS"), under the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 et. seq. (1999), in connection with all GMO submissions. Such a submission will ensure that environmental impacts of any GMO food are considered. In making this request, NNFA adds that FDA should defer to the United States Department of Agriculture ("USDA") and/or the Environmental Protection Agency ("EPA") in evaluating the EIS submissions, as these agencies already have review mechanisms in place.

Second, NNFA asks that FDA require that all raw materials and ingredients/foods containing or produced by GMOs be identified throughout the chain of commerce, from seed to finished product, as containing or produced by GMOs. It is only in this manner that traceability can be ensured, and consumers can be correctly informed if consumer product labeling is required, or voluntarily provided.

I. Summary of NNFA's Citizen Petition

NNFA's Citizen's Petition is based on the Association's assessment that the informal consultation process detailed in the1992 GMO Foods Policy is inadequate to fully ensure the safety of these novel ingredients. NNFA detailed three specific flaws with the 1992 Policy:

(1) the consultation process being utilized by FDA is voluntary rather than mandatory, and thus risks omitting consideration of many ingredients in this novel category;

(2) the substantial equivalence presumption that FDA applies to many GMO foods lacks well-defined assessment criteria; and

(3) the process outlined by the agency lacks the transparency needed to allow scientific experts to independently assess the safety of these foods.

NNFA's Citizen Petition urged the agency to replace its 1992 GMO Foods Policy with one that would:

(1) mandate that any manufacturer claiming GRAS status for a new GMO food make a pre-market safety data submission that is evaluated by the agency under defined risk assessment standards. NNFA urged the agency to consider allergenicity, toxicity and unexpected effects of GMO foods and food additives in any safety assessment; and

(2) provide transparency by affording independent scientific experts and other interested persons the opportunity to examine and comment upon relevant safety data in such a submission.

At this time, there has been no FDA response to the NNFA Citizen Petition.

II. Additional Measures That Should Be Taken by FDA

A. FDA Should Require A Valid Programmatic Environmental Impact Statement In Conjunction With Each GMO Submission

As noted in its December 20, 1999 Citizen Petition, NNFA is concerned about the unintended effects of GMO plants and foods, including potential ecological and environmental effects. Toward this end, NNFA asks FDA to amend its policy on GMO foods to require that each GMO submission be accompanied by a programmatic EIS under NEPA. In implementing such a requirement, NNFA suggests that FDA defer the responsibility for assessment of the EIS to USDA and/or EPA, agencies that currently have considerable experience in evaluating such material.

NEPA is designed to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man" 42 U.S.C. § 4321, and to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 42 U.S.C. § 4332. To accomplish its aims, NEPA requires that an EIS be prepared by federal agencies for every federal action significantly affecting the quality of the human environment.

GMO plants and foods represent an unprecedented step in the history of food development. Through recombinant techniques, genes can now be transferred between unrelated species and even between animals and plants. In this manner, GMO plants and foods introduce ecological entities that have previously not existed and thus have the potential for any range of impacts on the existing environment.

FDA takes the position that an EIS is not required in its reviews because foods do not *themselves* trigger the environmental concerns mandating the EIS. 57 Fed. Reg. 22984, 23005 (1992). All of the GMO foods that have passed through FDA's consultation process are plants or plant derived ("Foods Derived from New Plant Varieties Derived Through Recombinant DNA Technology: Final Consultations Under FDA's 1992 Policy," CFSAN, December 2000) and clearly plants themselves are components of the environment and its ecology. Based on confirmed scientific assessments, it is clear that an EIS requirement is warranted for these substances. (See Exhibit B to NNFA's December 20, 1999 Citizen's Petition).

The additional burden to FDA in adding an EIS requirement is not large. USDA and EPA already evaluate EIS submissions in conjunction with their review of GMO products. NNFA suggests that in implementing an EIS requirement, the agency can defer to USDA and EPA, agencies with considerable experience reviewing such materials. This sharing of resources is contemplated by the Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50856 (1984).

B. GMO Foods Should Be Identified Throughout the Chain of Production So that Accurate Labeling Is Available

In its second additional request, NNFA asks FDA to make the identification of GMOs and GMO-containing products mandatory throughout the chain of production. In light of recent events, NNFA believes that traceability of GMOs in foods is of utmost importance. By requiring identification of such information throughout the chain of production, the tracing of GMO-containing products can be accurately carried out. Currently, there is no effective tracking mechanism in place.

The presence of GMOs in foods is also of great concern to the majority of American consumers. A September 1999 poll for the Grocery Manufacturers of America found that 92% of all Americans support the labeling of all GMO foods. A Time Magazine poll also found that the majority of the population would like to know whether a food contains GMOs. (Margot Roosevelt, Taking it to Main Street, Time Magazine, July 31, 2000). FDA's own hearings on GMO foods, carried out throughout the autumn of 1999, also

demonstrate that a large vocal portion of interested parties would like to have the information that would allow them to make a choice about consuming these products.

The labeling of finished product may therefore become a necessity to address this consumer demand. In adopting NNFA's recommendation, the burden of determining whether a product contains GMOs is placed not on a finished product producer who chooses to voluntarily label products as GMO-free (or who is required to by some future law), but on those who can more readily determine whether the products contain GMOs.

For the foregoing reasons, NNFA respectfully requests FDA to respond to its December 20, 1999 Citizen Petition, and incorporate these two additional recommendations into its analysis.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION

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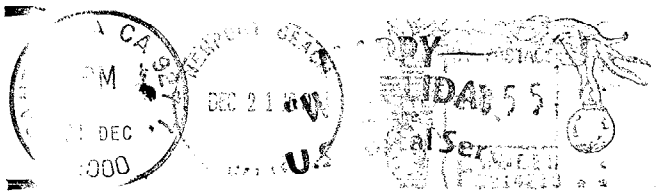
NNFA
National Nutritional Foods Association



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