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April 18, 2002

**CERTIFIED MAIL**

Docket's Management Branch  
Food & Drug Administration  
Room 1061  
5630 Fisher's Lane  
Rockville, Maryland 20852

Re: Citizen Petition

To Whom It May Concern:

Enclosed, please find a Citizen Petition to be filed pursuant to Title 21 of the Code of Federal Regulations. The petition is being submitted by the Ginseng Board of Wisconsin in order to halt the distribution and sale of any ginseng or products containing ginseng in the United States, if said ginseng or products containing ginseng contain any amount of the pesticide chemical residue Pentachloronitrobenzene ("PCNB"), also known as "Quintozene."

Please acknowledge receipt and filing of this petition on the enclosed copy of this letter and return it to me in the enclosed envelope.

Thank you for your time.

Cordially,

Gregory J. Strasser  
STRASSER & YDE, S.C.

GJS/mal  
enclosure

02P.0176

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# CITIZEN PETITION

The undersigned submits this petition under §408(1)(A) of the Federal Food, Drug, and Cosmetic Act, to request the Commissioner of Food and Drugs to issue an order consistent with the action requested herein.

## **A. Action Requested**

The petitioner respectfully requests that the Commissioner enter an order of enforcement “prohibiting the distribution or sale of any ginseng or products containing ginseng in the United States if said ginseng or products containing ginseng contain any amount of the pesticide chemical residue pentochloronitrobenzene (‘PCNB’) also known as ‘quintozene’ and further requiring all imported ginseng and products containing ginseng to be stopped at the border, tested for pesticide chemical residues, and prohibiting any said products from leaving Customs for receiver warehouses until testing has been completed.”

## **B. Statement of Grounds**

The Food and Drug Administration has power under the Federal Food, Drug, and Cosmetic Act to establish “tolerances” for the presence of pesticide chemical residues in/on food, including raw agricultural commodities. Specifically, CFR §408(1)(A) states, in pertinent part, that “any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless [...] a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance.”

A review of the FDA’s Glossary of Pesticide Chemicals, shows that pentochloronitrobenzene (“PCNB”), commonly known as “quintozene,” has a tolerance established under 40 CFR §180.291, and is used in foreign countries. §180.291 establishes a tolerance for PCNB of “0.1 part per million [...] in or on the raw agricultural commodity cottonseed.” The section also establishes tolerances of 0.2 parts per million for collards, kale and mustard greens. However, §180.291 makes no mention of an established or accepted tolerance level for PCNB residue in or on ginseng. Under §408(1)(A), the absence of an established tolerance level for a particular pesticide chemical residue means that the presence of such pesticide chemical residue in or on a food shall be deemed unsafe.

The Ginseng Board of Wisconsin made random purchases of ginseng and ginseng products from various stores and distributors throughout the State of Wisconsin and in the states of California and New York. Tests performed on these random samples showed that each product tested contained PCNB pesticide chemical residue. As is shown in the attached test results, obtained by the Ginseng Board of Wisconsin, the level of PCNB found in 46 random samples of ginseng ranged from a low of less than 10.0 parts per billion (or 0.010 parts per million) to a high value of 8700 parts per billion (8.70 parts per million), with only four samples between .1 and .2 ppm, and another four

samples below .1 ppm. Only 8 of the 46 samples tested had PCNB levels of less than 10.0 ppb (0.010 ppm), and may possibly be considered “clean.” The average PCNB level of the 38 “dirty” samples was a staggering 1164.329 ppb (1.164329 ppm). The fact that any amount of PCNB was detected indicates a violation of the Federal Code, notwithstanding that the vast majority of samples (30 samples out of 46 tested) exceeded even the higher 0.2 ppm tolerance level for other agricultural commodities, and the overall average of the 38 “dirty” samples was nearly *six times* the 0.2 ppm permissible limit.

Additionally, there is some concern that there is widespread adulteration and mislabeling or misbranding occurring in the sale of ginseng. 21 USCS §331 prohibits the “introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” It also prohibits the “receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.” According to §342(a)(2)(B), a food shall be deemed to be adulterated if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title” (the Federal Food, Drug, and Cosmetic Act). As already illustrated, the PCNB detected in the ginseng samples submitted by the Board are considered unsafe under the FD&C Act by virtue of the fact that a tolerance level has not been established for ginseng.

Indeed, in a letter to James Riehle, President of the Ginseng Board of Wisconsin, dated November 2, 2001 (also attached), the Director of the Office of Nutritional Products, Labeling and Dietary Supplements, and the Center for Food Safety and Applied Nutrition, Dr. Christine Lewis Taylor, indicated that PCNB has been found in a variety of ginseng products from several countries, primarily Canada, China and Korea. Dr. Taylor further indicated that their sampling results “indicated that several products contained pesticide residues, primarily quinterozone and procymidone, for which tolerances are not established. Because no tolerances for these pesticides in ginseng have been set, the products containing them violated the Federal Food, Drug, and Cosmetic (FD & C) Act, and the affected shipments were denied entry into the United States.” Unfortunately, as the attached test results indicate, there is reason to believe that there is still widespread sale of ginseng and ginseng products being sold in the United States which contain PCNB residue.

In addition, there are potential violations of Federal law regarding the misbranding of these Ginseng products. 21 USC §343 states that “a food shall be deemed to be misbranded if its labeling is false or misleading in any particular, [...] or if it is offered for sale under the name of another food, [...] or if its container is so made, formed, or filled as to be misleading.” Thus, it can be argued that “Wisconsin Ginseng” is being misbranded in violation of Federal law. In other words, any ginseng labeled “Wisconsin Ginseng” that contains PCNB is misbranded, because Wisconsin Ginseng (as opposed to Canadian, Korean or Chinese Ginseng) cannot be treated with PCNB as a matter of law.

Pertinent references have been attached, including Federal passages cited above, the letter from Dr. Taylor, dated November 2, 2001, as well as the test results obtained by the Ginseng Board of Wisconsin.

**C. Environmental Impact Statement**

No environmental impact statement is required with this petition, as petitioner does not seek approval of food or color additives, drugs, biological products, animal drugs, or a medical device, or for a food to be categorized as "generally recognized as safe."

**D. Economic Impact Statement**

Economic impact statement not requested by the Commissioner as of this time.

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

James P. Gill  
Signature *PWS.*

April 16, 2002  
Date

Ginseng Board of Wisconsin  
Name of Petitioner

Representative of Ginseng Industry  
Title of Petitioner *in Wisconsin*

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