



Council for Responsible Nutrition

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December 16, 2005

Documents Management Branch
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

Re: PYRIDOXAMINE--Citizen Petition, Docket No 2005P-0305 and Comment requested (70 FR 69976-7, dated November 18, 2005)

Dear Madam or Sir:

The Notice of opportunity to comment published in 70 FR 69976-7 (November 18, 2005) requested information that "bears on pyridoxamine's prior marketing as a dietary ingredient or as a food, as well as other information that would inform the agency's final decision on the status of pyridoxamine." The notice also indicated a deadline of December 19, 2005 for comment.

Our understanding of the Dietary Supplement Health and Education Act and the Citizen's Petition is that two issues are germane--(1) whether pyridoxamine is a dietary ingredient, and (2) whether it was marketed as a dietary supplement prior to October 15, 1994.

In response to these issues, our comments are:

1. Pyridoxamine is unequivocally a dietary ingredient because it is one of the three primary natural forms of vitamin B6, and it is pyridoxine occurs commonly in animal products used as human foods.¹
2. There is very strong evidence that pyridoxamine was marketed as a dietary supplement prior to October 15, 1994, and is therefore an "old" dietary ingredient under the Dietary Supplement Health and Education Act (DSHEA). As such, pyridoxamine is not subject to the seventy-five day dietary ingredient notification provisions of DSHEA. In early 1995, during the six-month period immediately following the enactment of DSHEA,

¹ For example, see Leklem, in *Modern Nutrition in Health and Disease, 9th Ed.*, Williams & Wilkins, Baltimore, 1999.

CRN and other trade associations surveyed their members and created lists of "old" dietary ingredients to memorialize those dietary ingredients that were being marketed prior to the passage of DSHEA. Pyridoxamine is on these lists, both as a form of vitamin B6 and as a separate ingredient.

Since November 18, 2005, CRN has contacted its members and other companies that might have sold pyridoxamine as a dietary supplement before October 15, 1994. We have identified two companies whose former employees believe they marketed pyridoxamine during that era. Because of the age of relevant records, the search for documentary evidence is proving difficult and tedious. The relevant records include order forms, sales records, catalogs, or any other documents that show sale of pyridoxamine as a dietary supplement ingredient. All dates before October 15, 1994 are relevant. During this period many records were never in electronic form and many have been put into long-term storage, with some in microfiche form. Given these facts, a comprehensive search is going to take longer than we, or apparently the Food and Drug Administration, had anticipated. The companies to have such agreed to perform these labor-intensive searches, but will need sufficient time to complete the task.

It is very important for the Food and Drug Administration (FDA) to give ample time for a detailed search of the relevant records. If FDA should decide that pyridoxamine is excluded from the dietary supplement definition because of lack of evidence that it was marketed as or in a dietary supplement before October 15, 1994 and we are able to locate documentary proof of such sales, FDA would be obligated at that time to reverse itself. Such reversal would not be in the interest of the public, manufacturers, or FDA.

Given the importance of the issue as well as the age of the requested records, the retirement of many persons with pertinent experience, and the inherent difficulty in searching stored, non-electronic records, we request a 90-day extension of the comment period.

Sincerely,

A handwritten signature in cursive script, appearing to read "John N. Hathcock".

John Hathcock, Ph.D.
Vice President