



## Council for Responsible Nutrition

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September 14, 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/CP1

Dear Madam or Sir:

This letter is to request that the Food and Drug Administration (FDA) deny the Citizen Petition on pyridoxamine submitted by counsel for BioStratum, Inc. on July 29, 2005. That petition requested that FDA (1) declare that dietary supplements containing pyridoxamine are adulterated as being an unapproved "new dietary ingredient"; (2) remove all dietary supplements containing pyridoxamine from interstate commerce, and (3) not place that petition in the Docket for Premarket Notifications for New Dietary Ingredients.

The Council for Responsible Nutrition (CRN) submits this letter to request that FDA deny the BioStratum petition for two substantive and sufficient reasons:

1. Pyridoxamine is unequivocally a dietary ingredient because it is one of the three primary natural forms of vitamin B6, and it is one of the two predominant forms in animal products used as human foods<sup>1</sup>.
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, CRN surveyed its members and created a list of "old" dietary ingredients to memorialize

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

those dietary ingredients that were being marketed prior to the passage of DSHEA. Pyridoxamine is on that list. CRN will gladly provide documentation of this fact, along with appropriate affidavits to that effect upon request. This listing by CRN of pyridoxamine as a dietary ingredient marketed prior to 1995 is entirely consistent with the long history of the science of this form of vitamin B6.

In consideration of these facts, FDA is obligated to reject the BioStratum petition.

Sincerely,

A handwritten signature in black ink, appearing to read "John N. Hathcock". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

John Hathcock, Ph.D.  
Vice President