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**PYRIDOXAMINE DECISION PLACES MORE RESPONSIBILITY ON INDUSTRY  
—CRN Encourages Companies to Keep Careful Ingredient Records—**

WASHINGTON, D.C., *January 28, 2009* — *In response to the Food and Drug Administration's (FDA) decision that products containing pyridoxamine dihydrochloride are not dietary supplements under the Dietary Supplement Health and Education Act (DSHEA), the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement.*

**Statement from Andrew Shao, Ph.D., vice president, scientific and regulatory affairs, CRN:**

“CRN accepts as established law under DSHEA the requirement that an article that has been authorized for investigation as a new drug and subjected to substantial clinical investigation prior to its being marketed as a dietary supplement or a food may not be marketed as a dietary supplement. However, we are disappointed with FDA’s response to the recent citizen petition involving pyridoxamine (a form of vitamin B6) that apparently views as inadequate the evidence presented by the industry, including CRN, of the previous marketing of pyridoxamine, even prior to the passage of DSHEA. FDA’s decision suggests that companies need to produce even more extensive evidence supporting an ingredient’s marketing as a dietary supplement, including catalog and business records from more than 15 years ago. Demanding that industry maintain these records, but failing to work with industry to develop an agreed-upon list of ‘grandfathered ingredients,’ places more burden on dietary supplement companies to be sure that they can substantiate that an ingredient has in fact previously been marketed as a dietary supplement.

The Agency’s decision on pyridoxamine could set a precedent for the status of other dietary ingredients to be challenged. As such, CRN strongly encourages supplement and food companies to keep careful records of ingredients and marketing materials to ensure that the ingredients that they are using and marketing can continue to be marketed as dietary supplement ingredients under the law.”

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**Note to Editor:** The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. CRN members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN’s Code of Ethics. Visit [www.crnusa.org](http://www.crnusa.org).