PHARMAVITE

5243 '03 SEP 22 A9:31

September 19, 2003

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

Re: Docket 2003N – 0314

Dear Sir or Madam:

In response to the request for public comment published in the Federal Register on July 23, 2003 regarding the burden of notifying the Agency of the use of "structure/function" claims on dietary supplements, we submit the following comments.

The Agency requested comment in four areas:

1. Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

   We believe the collection of information is necessary as a requirement of the Dietary Supplement Health and Education Act.

2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

   We believe the Agency's estimate of the burden to be reasonably accurate.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

   We believe the specific information required in these submissions is appropriate and sufficient for the Agency to perform their regulatory duties.

4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, or other forms of information technology.

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We believe the burden could be eased slightly by the ability to supply required information though an electronic form created by the Agency, perhaps submitted through the Agency's website. In addition to the information currently required, it would be beneficial if such a form could include the ability for the notifier to include a reference number.

Sincerely,

David Kropp ak

David Kropp
Director, Regulatory and Consumer Affairs

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