National Nutritional Foods Association

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Dockets management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

October 4, 2001

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey, [Docket No. 01N-0319], 66 Fed. Reg. 41245, August 7, 2001.

Dear Sir/Madam:

The National Nutritional Foods Association (NNFA) submits the following comments regarding Agency Information Collection Activities; Proposed Collection, Comment Request; Health and Diet Survey, published on August 7, 2001, at 66 Fed. Reg. 41245. NNFA is the oldest and largest, non-profit trade organization dedicated to protecting and advancing the natural products industry. Our members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics.

FDA invited comments on:

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.*

NNFA is committed to supporting the continued development, marketing and use of safe dietary supplements. Our members view FDA as the principal agency with both regulatory and enforcement responsibility for dietary supplements. Therefore, we support FDA's effort to develop a health and diet survey to ensure that safe and appropriately labeled dietary supplements continue to reach consumers as long as the education programs and enforcement policy developed as a result reflect the framework established by the Dietary Supplement Health and Education Act of 1994 (DSHEA).

DSHEA was based on the desire of consumers to educate themselves on the health benefits related to particular dietary supplements. Additional insights into consumers' knowledge about dietary supplements and the effectiveness of labels as one method for delivering educational information, such as structure/function claims, is welcome and should benefit public health. Using this information to develop consumer education programs, with assistance from stakeholders, is certainly a function of FDA.

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3931 MacArthur Blvd., Suite 101 • Newport Beach, CA 92660 • (949) 622-6272 • Fax (949) 622-6266 • www.nnfa.org

However, the supplement industry continues to be unjustly challenged as "unregulated" by the press, which uses FDA's lack of an enforcement record against supplements as a cornerstone for such argument. NNFA is concerned that any further development of regulatory policy reinforces this argument if the policy goes unenforced. We suggest then that survey information can only have practical utility when used to develop policies consistent with DSHEA, if they are ultimately enforced.

As a final point, survey data assessing adverse experiences with dietary supplements should only serve as a starting point for the Agency to focus on the proper collection and evaluation of adverse experiences and not be used to malign particular products or DSHEA.

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

NNFA would like to assist the Agency with developing and reviewing the survey questionnaire. As a trade association that routinely surveys our members and the industry we have a fair amount of experience conducting surveys. We have learned that allowing significant stakeholder input is vital to enhancing the quality and utility of information collected. This is especially important because, as your federal register notice states, survey results will be used to develop consumer education programs and regulatory policies that will impact the health and wellness of consumers.

Additionally, questionnaire construction has elements that often appear to be common sense but actually involve a great deal of subtlety. This is especially true for the natural products industry where some products may not be accepted as part of the traditional health care paradigm. Industry input will assist to pinpoint these subtle areas and result in more reliable and valid results, and ultimately a better understanding of the consumer who is the intended beneficiary of labeling and education initiatives.

In order to provide additional assistance, NNFA would also appreciate the opportunity to review survey results as soon as feasible after their collection. This will allow industry an opportunity to work with FDA to interpret the information collected and is more likely to result in education programs and regulatory policies that we can support. Therefore, the practical utility of the survey is increased.

NNFA appreciates the opportunity to file these comments and FDA's effort in this area.

Respectfully Submitted,

David R. Seckman

David Seckman
Executive Director/CEO

From: Kim Smith (949)622-6272
National Nutritional Foods Assn
3931 MacArthur Blvd
Suite #101
Newport Beach, CA, 92660

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