DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 2 3 2007

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for the letter of April 4, 2007, regarding your concern about the lead content of dietary supplement vitamin products and the regulation of those products by the Food and Drug Administration (FDA or the Agency).

In your letter, you asked for a response to four specific questions, which are re-stated below, followed by the Agency's response.

1). What steps has FDA taken in response to the Consumerlab.com findings of lead contamination in the Vitamin Shoppe women's multivitamin?

Response: As you know, on January 19, 2007, ConsumerLab.com reported that *The Vitamin Shoppe® Multivitamins Especially for Women* were contaminated with 15.3 micrograms of lead per daily serving. The Vitamin Shoppe subsequently stated that it has removed stocks of the product from the market.

Through its online subscription service, which is available for $10.00, ConsumerLab.com provides only a single numerical result of its analysis of The Vitamin Shoppe product and indicates whether it exceeds the lead limit set by ConsumerLab.com. That information is insufficient to enable FDA to reach any conclusions about the validity of the tests performed by ConsumerLab.com or to inform Agency deliberations as to the need or scope of any follow-up action that might be warranted. FDA's Center for Food Safety and Nutrition has contacted ConsumerLab.com to obtain more information on the analytical results of its testing of the Vitamin Shoppe women's multivitamin. We have received additional, but limited, information concerning the identity of the product and some of the sample collection, preparation, and analytical procedures.

FDA also has followed up with The Vitamin Shoppe. However, this matter is open and still under review. Therefore, we are unable to provide additional details at this time.

2). What steps does FDA plan to take to address the issue of lead contamination in vitamins by any manufacturer?

Response: In 2003, FDA convened a group to undertake a broad survey of products thought to have the highest potential for daily lead consumption, including prescription and over-the-counter drugs, dietary supplements and vitamins. Forty-five products were tested by FDA laboratories using state-of-the-art analytical procedures. Full results of this analysis will be published soon.

Our follow-up with The Vitamin Shoppe is intended to obtain information about the product formulation and how the contaminated product came to be marketed in the United States. Such information will be useful to the Agency in focusing its investigational and laboratory resources most effectively if it is determined that further action is warranted. We believe that a clearer understanding of the facts in this case is needed before decisions can be made on what additional steps may be necessary.

3). Does FDA need additional legal authority to respond to the Consumerlab.com findings? If so, what additional authority would be necessary for FDA to respond effectively?

Response: The Agency believes that it currently has adequate legal authority to respond to findings of potentially adulterated dietary supplements being marketed to consumers in the United States. We have the authority to take action against products that contain unsafe levels of contaminants such as lead.

4). Does FDA need additional resources to respond to these findings? If so, what additional resources would be necessary for FDA to respond effectively?

Response: At the present time, FDA does not conduct routine surveillance testing for heavy metals in dietary supplements. FDA does conduct a surveillance program for toxic elements in foods based on a sample schedule that focuses on a different commodity type each year. Although that program is already underway for fiscal year (FY) 2007, FDA will examine whether dietary supplements should be considered for inclusion in the sampling schedule for FY 2008. If dietary supplements were to be included in the FY 2008 program, the Agency would likely need to defer the testing of other commodities to a later year. The Agency has not conducted an estimate of the costs to complete this testing.

Thank you for your interest in this matter. If we can be of further assistance, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation