ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

July 27, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food and drug supply.

One area that concerns us is the safety of dietary supplements. The dietary supplement industry is a $22 billion industry. Unbelievably, it has taken FDA more than 10 years to establish any good manufacturing practices regulations for the industry.

Recently, FDA issued a final rule establishing regulations to require current good manufacturing practices for dietary supplements. This rule applies "to all domestic and foreign companies that manufacture, package, label, or hold dietary supplements." This rule requires manufacturers "to evaluate the identity, purity, strength, and composition of their dietary supplements." As part of this rule, manufacturers are required to test ingredients and the finished product. However, under an interim final rule, a manufacturer can petition FDA for an exemption from the 100 percent identity testing requirements. This exemption is very troubling because FDA will not be able to assure the safety of these untested dietary supplements.

We are particularly concerned about the safety of dietary supplements and their ingredients coming into the United States from certain countries including China and India. Much of the global supply of vitamins is now manufactured in China. In fact, in the last decade, China has captured 90 percent of the market for vitamin C and provides a majority of vitamins A, B12, and E. China also produces much of the world's amino acids, enzymes, and minerals. The

thought of many of these dietary supplements entering into the United States without being tested is disturbing. One former FDA research scientist, who tests thousands of dietary supplements each year, believes that approximately 25 percent of dietary supplements he tests do not meet quality or safety standards.

The recent example of melamine-contaminated wheat gluten imported from China into the United States illustrates why it is vital that all dietary supplements and dietary supplement ingredients should be tested before entering the United States. ChemNutra, the importer of this wheat gluten, is primarily a dietary supplement importer. The Chinese firm, who provided this wheat gluten to ChemNutra, intentionally contaminated the wheat gluten with melamine. Thus, it is not beyond the realm of possibility that Chinese firms might be sending unsafe and adultered dietary supplements and their ingredients into the United States.

In order to assist the Committee in its investigation of the safety of the Nation's food and drug supply, we request that you provide the Committee with the following information regarding FDA's regulation of dietary supplements:

1. The contaminated wheat gluten imported by ChemNutra was never inspected by the agency because the Operational and Administrative System Import Support did not designate wheat gluten as a high-risk product. Given that ChemNutra is primarily a dietary supplement provider and that wheat gluten can be used as an ingredient in dietary supplements, as soon as you learned about the contaminated wheat gluten, why did you fail to issue an import alert on all dietary supplement ingredients coming from China?

2. Why, given the recent scandals involving Chinese imports of vegetable proteins, fish, and toothpaste, does FDA not require all importers of dietary supplements to test a scientifically valid sample of each shipment either before shipping such products for retail sale or as intermediary goods for inclusion in products intended for human consumption or animal feed?

3. Does the agency think imports or untested dietary supplements and dietary supplement ingredients from countries with minimal safeguards such as China and India are safe for Americans to consume?

4. How will the agency determine if untested dietary supplements and dietary supplement ingredients are safe?

5. If dietary supplements are not tested, how will the agency determine if the product is labeled correctly?
6. If dietary supplements are not tested, how will the agency determine if the product is as potent as claimed?

Please supply all requested information by no later than the close of business August 10, 2007. If you have any questions relating to this request, please contact us or have your staff contact David Nelson or Kevin Barstow with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations