Congress of the United States
House of Representatives
Washington, DC 20515

January 31, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, Maryland 20857

Dear Dr. Schwetz:

We are writing to express concern about recent media accounts that consumers could be exposed to bovine spongiform encephalopathy (BSE) from dietary supplements.

According to a January 19, 2001, ABC news report, despite a ban on the importation of certain bovine products from Europe, bovine-derived dietary supplement ingredients or dietary supplements that contain bovine-derived material may have been imported from countries where BSE exists before the ban went into effect. These products could contain BSE-infected material.

Dietary supplements, unlike prescription drugs or vaccines, require no pre-market approval and no post-market surveillance. This makes it more difficult for the Food and Drug Administration (FDA) to adequately oversee what products are being sold, where the products and the products' ingredients originate, and which products may contain potentially dangerous materials.

Tainted supplements could find their way into the United States through a number of different routes. For example, over the past several years, staff has spent considerable time investigating how certain individuals are illegally selling and distributing drugs (including dietary supplements) via internet Web sites to a wide population in the U.S. Because many of these sites are distributing their products from offshore locations, both the origin and the quality of the products they ship are often unknown. Because these offshore sites continue to engage in these activities, and because some dietary supplements contain various animal-derived ingredients, it appears that certain supplements containing questionable ingredients could find their way to the United States.

We are interested in learning how the FDA is monitoring dietary supplement products that may contain bovine-derived material and how the FDA is handling the potential risk of exposure to BSE-infected materials. We would like answers to the following questions:

1. Does the FDA know how many supplement products that are currently being marketed in the United States contain bovine-derived material?

2. Does the FDA know whether there are any dietary supplements containing bovine-derived materials, or bovine-derived supplement ingredients, currently being marketed in the United States that have been imported from countries where BSE exists? This includes products or ingredients that were imported before the imposition of a ban on certain ruminant products from countries with BSE.

3. If supplements or ingredients containing bovine-derived material marketed in the United States have been imported from countries that have BSE, what actions has the FDA taken to ensure that consumers are not at risk of exposure to BSE from dietary supplements?

4. How, if at all, is the FDA determining the origin of bovine-derived supplement ingredients or products?

5. What are the risks to humans of contracting new variant Creutzfeldt-Jakob disease from dietary supplement products that contain brain or glandular tissue?

Please contact us, or have your staff contact Sarah Despres at 225-5420 or Chris Knauer at 226-3400, if you have any questions about this request.

Sincerely,

Henry A. Waxman
Ranking Member
Committee on Government Reform

John D. Dingell
Ranking Member
Committee on Energy and Commerce

cc: The Honorable W. J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce

The Honorable Dan Burton, Chairman
Committee on Government Reform