June 4, 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:

My office has been contacted by a woman who had to undergo a kidney transplant after taking a dietary supplement product that contained aristolochic acid. I understand that there is a known association between aristolochic acid and kidney failure. According to information on your website, a hundred people in Belgium, and several people in the United Kingdom, may have suffered some kind of renal disease as a result of taking herbal preparations that contained aristolochic acid. I am interested in knowing what steps the Food and Drug Administration (FDA) is taking to protect consumers from these potentially dangerous products.

Specifically, I would like you to answer the following questions:

1. When did FDA first become aware that aristolochic acid could cause kidney damage?

2. When did FDA first learn that dietary supplements containing aristolochic acid were being sold in the United States?

3. How many adverse event reports relating to aristolochic acid have been reported to FDA?

4. How many of these reports are of serious events?

5. How has FDA followed up on these adverse event reports?

6. What actions has FDA taken to keep these products from entering the United States, including enforcement actions against retailers and manufacturers of supplements containing aristolochic acid?

7. Is FDA aware whether supplement products containing aristolochic acid continue to be sold in the United States and, if so, what does FDA intend to do about these products?

8. Are these products available on the Internet?

9. Aside from a notice on your webpage, what other steps has FDA taken to alert consumers to the dangers of dietary supplements that may contain aristolochic acid?

I would like this information by June 19, 2001. If you have any questions, please call Sarah Despres of my staff at (202) 225-5420.

Sincerely,

Henry A. Waxman
Ranking Minority Member

cc: The Honorable Dan Burton, Chairman
Committee on Government Reform