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Dr. Christine L. Taylor and Dr. Robert Moore
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition, Room 4C096
Mail Stop: HFS-800
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Dear Drs. Taylor and Moore:

As you know, Aristolochic Acid (AA) is an extremely hazardous chemical that is present in some herbal supplements. In humans, AA causes urothelial tract cancer and nephrotoxicity. Because of these health hazards, products with AA should not be available to consumers and should be immediately withdrawn from the marketplace.

In spite of the fact that FDA issued warnings about AA in 2000 and 2001 (<http://www.cfsan.fda.gov/~dms/ds-bot.html>) concerning the dangers of ingredients with AA, in early 2003 I found 112 products containing AA (or substituted by Aristolochia) for sale on the World Wide Web. I told you about this problem in a letter on March 4, 2003 (enclosed) and sent details of individual products and web sites. It is now three and a half months since my earlier letter, and I still find such products on the web . This is an urgent problem that requires prompt FDA action.

To indicate continued and current availability of AA products, Attachment A shows some additional products that can now be ordered that were not in my March letter. To show that the products I told you about earlier are still available on the Internet, Attachment B shows some web pages that I printed in June for a few products I had told you about.

Additionally, I ordered several products myself to see whether AA continues to be readily available, according to the list of ingredients. I indicate below the relevant ingredients that are listed on the bottle or package insert for products I have purchased. All are Chinese imports sold at US web sites.

I do not know whether FDA is currently pursuing an enforcement action regarding the information I sent to you in March. If so, this additional information may be helpful to you. If an enforcement action is not ongoing, then the results indicate the urgency of pursuing this problem and provide some particular products of concern.

Products I purchased from list of AA products in my letter of March 4, 2003

1. Long Dan Xie Gan Wan purchased from Angel Herb: Herbs for Health.
<http://www.talonsvcs.com/angelherb/tcm-clear-heat.htm>

The ingredients list states 7.14% Chuan Mu Tong on the Chinese side of the box. But the English side lists as 7.14% only the following: Scutellaria root, Angelica Dang Gui, Gardenia Fruit, Licorice root, HocQuartita stem, Plantago seed. At maxnature.com Long Dan Xie Gan Wan is listed as containing Caulis Aristolochiae Manschuriensis as an ingredienet (Guan Mu Tong).

2. Chuan Ke Wan purchased from Herbs West, bottle says product of Herbal Times
<http://herbswest.net/items/BL1355.shtml>

The ingredient list on the bottle includes Aristolochia fruit 2.00%.

3. Stephania tetrandra and Astragalus, Plum Flower Brand purchased from Herbswest.net
<http://www.herbswest.net/items/13341.shtml>

Stephania tetrandra root is listed in the ingredient list on the bottle.

4. Guan Xin Su He purchased from Angel Herb: Herbs for Health
<http://www.talonsvcs.com/angelherb/tcm-orifices.htm>

Only a Chinese language ingredient list is provided. Both on the bottle and in the package list there is no list of ingredients in English. On the web currently, a product named Caridioflex has the same Chinese name and is available at opane.com. The web page lists Aristolochia root as an ingredient.

5. Chi Kuan Yen Wan purchased from Angel Herb: Herbs for Health
<http://www.talonsvcs.com/angelherb/tcm-treat-arthritis.htm>

The bottle does not list any plant species known to contain or be substituted by Aristolochia species. In September 2001, Health Canada listed this product as containing Fructus Aristolochiae.

I would appreciate a prompt reply to this letter.

Sincerely,

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