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HERBAL MEDICINE

A Success Story on Aristolochic Acid

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The controversy surrounding aristolochic acid began in Belgium in the early 1990s, continued in England in the late 1990s, and proliferated in the United States in the new millennium. It is an incident that simply refuses to stay dormant. As such, practitioners must be aware of the latest medical and regulatory information.

In May 2000, the FDA placed an import alert on 63 herbs that "contain, may contain, or may be adulterated with aristolochic acid." Furthermore, the Food and Drug Administration (FDA) took the position that these herbs would be automatically detained and would be released only if an analytical exam proved that the herbs were free from aristolochic acid. As a result of this regulation, many valuable herbs and formulas were taken off the market.

With regards to the specific type of analytical exam of aristolochic acid, the FDA will only accept tests that use the liquid chromatography/tandem mass spectrometry (LC/MS/MS) method with precision of less than 0.5 parts per million (PPM). Hence, all other tests are not acceptable and are useless.

In compliance with FDA regulations, batches of herbs have now been successfully produced that have tested negative of aristolochic acid following the testing protocol established by the FDA. Lab results have confirmed that the herbs are free of aristolochic acid, with a precision of 0.25 ppm (which is lower than the FDA requirement. Furthermore, these results have been submitted to the FDA and the California Food and Drug Board (FDB). Both government agencies have acknowledged that the testing method is equivalent to the protocols established by the FDA, and the results (<0.25 ppm) are adequate and acceptable. The analytical reports and acknowledgement letters from the FDA and FDB may be obtained by contacting the author directly.

With this recent success, herbs and formulas that were once inaccessible will again be available. The example include, but are not limited to, stephania (*fang ji*); clematis armandi (*mu tong*); clematis (*wei ling xian*); and saussurea (*mu xiang*), as well as a variety of formulas such as *long dan xie gan tang*; *dang gui si ni tang*; *xi yi wan*; *ba zheng san*; *xin yi san*; and *xiao feng san*. This success is absolutely invaluable as we continue the fight to preserve and prescribe the herbs in Chinese herbal pharmacopoeia.

Although this matter is temporarily resolved, the issue is far from being settled. While there are some responsible and proactive companies, there are also some that are unaware of the FDA's position and continue to provide misleading information that their products are free of aristolochic acid (without using LC/MS/MS, or with precision of only 5 ppm, which is 10 times higher than the FDA's acceptable limit). Therefore, it is extremely important that the importers and practitioners are aware of these facts to be in full compliance with the FDA's rules and regulations.

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