Food

FDA Advises Dietary Supplement Manufacturers to Remove Comfrey Products From the Market

July 6, 2001

To: American Botanical Council,
American Herbal Products Association,
Council for Responsible Nutrition,
Consumer Healthcare Products Association,
National Nutritional Foods Association,
Utah Natural Products Alliance,
American Association of Oriental Medicine, and the
American College of Acupuncturists and Traditional Medicine.

The Food and Drug Administration (FDA) is issuing this letter to communicate to you our concern about the marketing of dietary supplements that contain the herbal ingredient comfrey (*Symphytum officionale* (common comfrey), *S. asperum* (prickley comfrey), and *S. x uplandicum* (Russian comfrey). These plants are a source of pyrrolizidine alkaloids that present a serious health hazard to consumers when they are ingested. FDA asks that you share this information with your members.

The use of comfrey in dietary supplements is a serious concern to FDA. These plants contain pyrrolizidine alkaloids, substances which are firmly established to be hepatotoxins in animals. Reports in the scientific literature clearly associate oral exposure of comfrey and pyrrolizidine alkaloids with the occurrence of veno-occlusive disease (VOD) in animals. Moreover, outbreaks of hepatic VOD have been reported in other countries over the years and the toxicity of these substances in humans is generally accepted. The use of products containing comfrey has also been implicated in serious adverse incidents over the years in the United States and elsewhere. However, while information is generally lacking to establish a cause-effect relationship between comfrey ingestion and observed adverse effects humans, the adverse effects that have been seen are entirely consistent with the known effects of comfrey ingestion that have been described in the scientific literature. The pyrrolizidine alkaloids that are present in comfrey, in addition to being potent hepatotoxins, have also been shown to be toxic to other tissues as well. There is also evidence that implicates these substances as carcinogens. Taken together, the clear evidence of an association between oral exposure to pyrrolizidine alkaloids and serious adverse health effects and the lack of any valid scientific data that would enable the agency to determine whether there is an exposure, if any, that would present no harm to consumers, indicates that this substance should not be used as an ingredient in dietary supplements.

Under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994, the manufacturer bears the primary responsibility for ensuring that its dietary supplement products are safe. FDA believes that the available scientific information is sufficient to firmly establish that dietary supplements that contain comfrey or any other source of pyrrolizidine alkaloids are adulterated under the Act. The agency strongly recommends that firms marketing a product containing comfrey or another source of pyrrolizidine alkaloids remove the product from the market and alert its customers to immediately stop using the product. The agency advises that it is prepared to use its authority and resources to remove products from the market that appear to violate the Act.

FDA also believes that manufacturers need to take adequate steps to identify and report adverse events, especially adverse events that may include liver disorders, associated with any product that contains an ingredient that may contain pyrrolizidine alkaloids. FDA recommends that firms promptly notify FDA's MEDWATCH program of reports of adverse events associated with the use of products containing any source of pyrrolizidine alkaloids.

All firms currently marketing products containing comfrey should also be aware of the fact that the Federal Trade Commission (FTC) has also taken action against unsafe products containing comfrey. The Commission recently announced an enforcement action it has brought against a firm for marketing comfrey-containing products. The Commission is challenging the safety and health benefit claims for a number of comfrey products sold by the firm. A stipulated preliminary injunction agreed to by the parties in the case prohibits the marketing of any comfrey-containing product intended for internal use or use on open wounds and requires a warning on comfrey products marketed for external uses. Information about the action is available through the FTC's web site.

FDA is available and prepared to assist the industry on these matters. Firms are encouraged to contact FDA if they have any questions or concerns about this important public health issue. Inquiries should be directed to Dr. Robert Moore in the Office of Nutritional Products, Labeling, and Dietary Supplements (202-205-4605; email rmoore2@cfsan.fda.gov).

Sincerely yours,

/S/

Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling, and Dietary Supplements

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Latest FTC Case in "Operation Cure.All" Focuses on Safety Risks of Comfrey Products Promoted Via Internet July 6, 2001

FTC Announces a Second Case Focusing on Safety Risks of Comfrey Products Promoted via Internet July 13, 2001