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Harmonizing North American Herbal Regulation: A U.S. Perspective.

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BASED ON A PAPER PRESENTED AT A SPECIAL SYMPOSIUM HELD AT THE 8TH INTERNATIONAL CONGRESS ON TRADITIONAL MEDICINE AND FOLKLORE ST. JOHNS, NEWFOUNDLAND, CANADA, AUGUST 20, 1994.

As we see in Canada, Mexico, and other parts of the world, there is growing interest in natural medicines -- particularly herbal products. In the U.S., current growth of the herbal products category is approximately 15-20% a year. Mass market retailers are now stocking and selling a large range of herbal dietary supplements and other natural remedies. Major U.S. pharmaceutical companies are closely studying the herbal marketplace with the view of launching their own natural product lines in the near future. Clearly, "natural" is in vogue. This rapid growth, however, has stressed and tested the current legal framework under which herbs are regulated.

Unlike Canada and Mexico, the U.S. Food and Drug Administration has not drafted specific policy statements or regulations to guide industry on safety or approval of herbs, good manufacturing practices, or the use of scientific evidence to support proposed claims for herbal products. Over the past several years, the FDA has expressed concerns that herbs are, in fact, drugs and, yet, are sold and regulated as foods. This view was clearly stated in a speech given by then FDA Deputy Commissioner for Policy, Michael Taylor, at the annual meeting of the Federation of American Societies for Experimental Biology in March of 1993. At that meeting, Mr. Taylor's speech included the following comments:

"One of the longest running public policy debates in Washington -- certainly within the province of the Food and Drug Administration -- is about to take center stage again . . . and it is about the role government should play in regulating dietary supplements

". . . The critical first step in defining the terms of the dietary supplement debate is to understand how broadly the term 'dietary supplement' is being used. The term is, unfortunately, being used without discrimination to refer to a very diverse spectrum of products that pose widely varying concerns and that may not all be subject appropriately to the same regulatory approachAs used in the Nutrition Labeling and Education Act and the dietary supplement debate, however, the term, "Dietary Supplement" is held to encompass, not only vitamins and minerals, but also herbs

" . . . From a scientific standpoint, the claimed benefits of many of these products are better evaluated in pharmacological rather than nutritional termsMany of the herbal and other botanical (or plant-derived)