

Codex Tsunami: FDA's Friedman Made No Bones About It..... How Soon People Forget.....

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On July 7, 1997 Acting FDA Commissioner Robert A. Friedman stated the following in a speech before the Senate Labor Committee:

FDA and the Global Marketplace: International Harmonization

The regulatory framework administered by the Food and Drug Administration (FDA) to provide public health and safety protection to American consumers is a model that many countries strive to emulate. At the same time, FDA recognizes that we operate in an increasingly more global, more interdependent market environment, and that American consumers can realize significant public health and economic benefits from efforts by FDA to share information, explore opportunities to collaborate on assessments and product reviews, and harmonize standards with its foreign counterparts. Growing demands on FDA's resources to assure the safety and efficacy of greater numbers of increasingly more complex products produced both here and abroad, absolutely mandate that FDA seek ways in which it can share its regulatory workload while maintaining public health protection for American consumers. Science driven harmonization can curtail duplication and thereby significantly reduce the cost of new drug development, in terms of the risks to which patients are exposed, the experimentation with animals, the regulatory costs to government and the cost to industry.

For many years, FDA has actively engaged in the kinds of information exchange that lay the foundation for the development and maintenance of high international standards, and pave the way for harmonization activities. We have entered into numerous Memoranda of Understanding (MOU) with other governments to ensure that their products intended for export to the United States adhere to our strict standards of health and safety protection. We also participate in limited and focused education and training initiatives that instruct others in how to conduct their activities so that products shipped to the U.S. will be in accord with U.S. requirements. We exert leadership in a number of international standard-setting organizations.

FDA has been a strong supporter of, and participant in, the Codex Alimentarius Commission (Codex). Codex is an international standards-setting organization for food safety composed of national governments from more than 150 countries. The work of Codex is increasingly important with the recognition of Codex as the relevant international standards-setting body for food safety in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) resulting from the Uruguay Round of multilateral trade negotiations.

Since its inception, Codex has developed in excess of 200 Commodity Standards, more than 40 codes and guidelines, about 2,500 pesticide/commodity maximum limits, and has reviewed the safety of over 500 food additives and contaminants. FDA, through its participation on most Codex Committees, provides scientific and regulatory expertise and forcefully presents U.S. views at the committee meetings.

FDA plans to amend its regulations and procedures for consideration of standards adopted by Codex. This action is being taken to provide for the systematic review of the Codex Standards in order to enhance consumer protection, promote international harmonization and fulfill obligations of the United States under international agreements.

In recent years, we have put considerable effort into the work of the International Conference on Harmonization (ICH), working closely with our regulatory counterparts in Japan and the European Union, as well as the three areas' organizations representing the major research and development pharmaceutical companies (e.g., the Pharmaceutical Research and Manufacturer's Association (PhRMA)). The goal of ICH is to harmonize across all three regions the requirements for data submitted to support safety, efficacy and quality determinations in new drug applications, and to develop guidelines for the industry based on the harmonized requirements. The past six years of effort have produced over 40 new harmonized guidelines, and another 20 are in various stages of development and review. The ICH effort is one of the best examples of a forward-thinking Agency that is willing to work not only with its regulatory counterparts, but with the regulated industry as well, to develop guidelines harmonized to the highest standards while also eliminating costly duplication of effort. Similar efforts are underway in the areas of medical devices and veterinary drugs.

Additionally, for the past three years we have been involved in negotiations to give limited recognition to inspections of drug and device facilities by European Union authorities and to expand the third party device review to include European Union notified bodies. A successful agreement has the potential to save resources for both sides, however, FDA must be satisfied that such an agreement would not compromise our responsibility for protecting American consumers.

I began this presentation outlining the Agency's accomplishments for two reasons: first, to demonstrate through concrete example that this Agency understands the importance of change. We have tried to be as responsive as possible to concerns expressed by Congress, consumers, and the industry and have undertaken reforms in response to these external criticisms. But change also has been driven by the Agency's own commitment to efficiently and effectively accomplish its mission. Five years ago few believed that we would be approving drugs in twelve months or less. Not only have we reached that goal, but we are now working cooperatively with industry to develop more open, cooperative and productive inspection procedures, and to restructure the regulation of tissue-based therapies to match regulation to risk. In each of these areas, and many others, we listen to the criticisms, engaged all of the stakeholders in defining the problem and worked with them on devising solutions that preserved and enhanced critical public health protections.