225-98-8003

MEETING BETWEEN SWISS AND UNITED STATES DELEGATIONS ON REGULATORY COOPERATION

Agreed minutes

Delegations of officials of the United States and Switzerland met in Washington, D.C., on July 9, 1998, to discuss strengthening regulatory cooperation between the health authorities of both countries in the fields of drugs, medical devices, and biological products. The discussions were held in a very open and constructive atmosphere and led to the following common understanding.

Both countries are committed to safeguarding the public health, enhancing public health protection, and reducing the regulatory burden in commerce in safe, effective and good quality drugs, medical devices, and biological products. Switzerland and the U.S. agreed to continue and enhance cooperation in the fields of drugs, medical devices, and biological products between the U.S. Food and Drug Administration (FDA) and the Swiss health authorities (Intercantonal Office for the Control of Medicines and Federal Office of Public Health), consistent with FDA's framework for achieving mutual recognition of good manufacturing practices inspections. (This framework was made public on May 10, 1998, and is available on the internet on FDA's home page.)

In order to achieve the goal of enhanced regulatory cooperation, a working program should be established between both countries and should contain as a first step the following elements, subject to the availability of resources and with maximum use of information already available on the Internet home pages of the participating regulatory authorities:

- intensifying/formalizing information exchange, in particular in the field of adverse reactions, quality defects and product recalls;

- provide Swiss authorities with access to COMSTAT (FDA's Compliance Status Information System) and provide for FDA's access to any similar electronic information system maintained by Swiss authorities;

- consider ways to build confidence in the other country's regulatory program as a first step toward more reliance on each other's activities; the following projects will be pursued:

  exchange of inspection findings (for instance form FDA 483) and inspection reports upon request;

use of joint inspections (for the purpose of observing each other's activities) and inspectional history, and

joint training of inspectors;

- promote the harmonization of technical requirements and auditing techniques;

- designation of contact points and definition of their respective tasks.

The plan is for a work plan to be agreed upon by the end of December 1998. Switzerland plans to forward a first proposal by the end of October.

Oscar Zosso, Ambassador
Head of Swiss Delegation

for Sharon Smith Holston
FDA Deputy Commissioner
for External Affairs

Washington, D.C.
August 7, 1998