information with foreign officials to include certain confidential commercial information, such as studies supporting product approval (57 FR 61598, June 26, 1992). The agency issued a final rule on November 19, 1993 (58 FR 61598) Section 20.89 as amended allows the agency, under specified conditions, to disclose confidential commercial information such as nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to foreign government officials who perform counterpart functions, without compelling the public disclosure of the information. The rule covers confidential commercial information submitted to the agency, or incorporated into agency-prepared records, as part of cooperative law enforcement or regulatory efforts. Under the amended regulation, several conditions must be met before FDA may disclose the information to the foreign government official. The conditions are the same as those proposed below with respect to analogous disclosures to State and local government officials.

One condition requires the foreign government agency to provide a written statement certifying its authority to protect the information from public disclosure and its commitment not to disclose the information without the written permission of the sponsor or written confirmation from FDA that the information no longer has confidential status. FDA requires this written statement to: (1) Include specified language; (2) bear the signature, name, and title of the responsible foreign government official; and (3) be submitted to FDA after the official is informed about the significance the agency attaches to the confidentiality of the information and understands that disclosure by the foreign government could constitute a criminal violation and would seriously jeopardize any further interaction between FDA and the foreign counterpart agency.

As discussed in the preamble to the 1993 final rule, that rulemaking was undertaken because FDA concluded that it needed to revise its public information regulations to disclose to foreign government officials confidential commercial information submitted to FDA or incorporated into agency-prepared records in order to provide clear authority for cooperation in reviews of pending submissions and other important international exchanges of regulatory information. The 1993 final rule facilitates the approval of products that are shown to be safe and effective, expedites the withdrawal of approval of products that are found not to be safe and effective, and enhances

the efficiency of FDA's enforcement efforts, while providing safeguards against public disclosures of proprietary information and conflicts of interest.

D. The Need to Extend to State Government Officials the Recent Changes in Provisions for Exchanging Confidential Commercial Information With Foreign Government Officials

FDA and State agencies work cooperatively and in a complementary manner to protect the nation's public health with regard to FDA-regulated consumer products. While States usually defer to FDA to approve the marketing of FDA-regulated products, some States actively regulate or monitor, within their State and under their own authorities, the clinical trials of some investigational new drugs, biologic products, and medical devices. In addition, most States have active enforcement programs, especially for foods.

FDA needs to be able to exchange information with State or local officials, without being limited to those who are commissioned or are under contract under § 20.88(a) and (b), FDA commissions State government officials, or enters into contracts with State agencies, primarily for the performance of cooperative regulatory work. However, certain cooperative efforts are more dependent on information exchange followed by coordination between Federal and State authorities, rather than on actual work performed by State authorities on behalf of Federal programs. In some regulatory efforts where the need for information exchange is paramount, FDA may be able to rely on FDA commissioned and contract employees in order to share confidential commercial information in the possession of FDA that is necessary to accomplish the agency's public health mission. But, as discussed below, commissioning and contracting, which are essential prerequisites under the current regulation, consume inordinate time and human resources and are not suited to dealing with information exchanges on rapidly developing problems.

Arrangements for issuing commissions are handled by State commission liaison officers located in FDA's regional offices. The commissioning process includes identifying suitable candidates (which often will require that supervisors or State agency heads also be commissioned), reviewing the candidates' qualifications to carry out activities specified in the commission, issuing certificates and credentials, and accounting for the credentials on a

periodic basis. FDA's experience has been that this mechanism is too rigorous, costly, and time-consuming to enable the rapid exchanges of confidential information with State government officials that are essential in public health emergencies and investigations. Furthermore, the State government official who is commissioned, and therefore permitted access to confidential commercial information in FDA's possession, is frequently not the employee who, in any particular case, is best capable of analyzing or evaluating the nonpublic information.

Similarly, contracting projects are not suited for cooperative Federal-State regulatory efforts requiring rapid exchange of information. Contracts are solicited, negotiated, and put in place according to formal U.S. Government contracting procedures; for continuing work, contracts must be renewed annually. In addition to being timeconsuming to establish, contracts cannot be relied upon to cover all FDA program areas. The services most commonly procured by FDA through contracts with the States are for establishment inspections, with related collection and analysis of samples, report preparation, and followup activity undertaken by the State agency under its own authority and program. FDA program areas are not covered uniformly across the States, with FDA having contracts in many (but not all) States for food inspections, but in only a few States for drug, biologic product, and medical device inspections.

The following are examples of situations in which the ability to share confidential commercial information with State governments in a less encumbered manner would have allowed more timely review of significant public health issues, or would have enhanced the effectiveness of regulatory activities:

1. FDA and some States acquire information from ongoing clinical investigations of new drugs, biologic products, or medical devices, including unanticipated adverse reaction or device malfunction data, clinical protocols, identities of study sites, and names of clinical investigators. When problems occur that could have an impact upon the safety of study subjects, public health decisions concerning the continuation of the study must be based upon the most complete information possible. This is facilitated by access to records at the study sites, and in certain situations it would be consistent with public health protection for State officials to have access to records that