FDA must evaluate in its review of the problem.

Under the existing regulations, State government officials can share information that they receive or acquire with FDA. However, because information concerning investigational drugs and medical devices is often confidential commercial information, FDA cannot reciprocate, unless the State officials are commissioned or under contract for law enforcement purposes. As explained above, the processes for issuing commissions to State government officials or placing them under contract are so cumbersome and time-consuming as to impede joint Federal-State efforts on clinical trials in progress that require a two-way exchange of relevant information. Such restrictions on the exchange of this information can hinder decisionmaking, for both FDA and State governments, where timeliness is important to protecting public health.

Further, State governments, on occasion, have not had ready access to information about pending FDA regulatory actions concerning clinical trials in progress that may involve health care institutions or individuals which operate under State licenses, permits, or registrations. In such circumstances, the current impediments to full-information exchanges thwart effective, coordinated regulatory solutions to public health problems. For example, in the case of Narcotic Treatment Programs (NTP's), FDA coordinates actions with the State agencies charged with regulating these types of clinics. Such coordination is essential because if FDA plans enforcement action that would close a program, the assistance of the State agencies is necessary to minimize disruption to the treatment of patients. The rapid exchange of nonpublic information can also enhance protection of the public health when a State has broad authority to require an unsafe or violative establishment within its borders to cease operations.

2. Both FDA and State agencies have responsibilities for Institutional Review Boards (IRB's), which are the boards or committees formally designated by institutions to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving use in human subjects of FDA-regulated products (21 CFR § 56.102(g)). In the case of noncompliant IRB's, FDA regulations allow the agency to notify relevant State and Federal regulatory agencies and other parties with a direct interest about any action FDA may take against the IRB or its parent institution (21 CFR 56.120). In

some instances, State action against violations may be preferable to Federal action, or a State may have authority to expeditiously revoke the license of a program or clinic operating under that violative IRB. However, State officials may need access to confidential information about the protocol or investigational product, including nonpublic confidential commercial information contained in IND's and NDA's, in order to take effective action. This proposed rule would permit FDA to share such information, where the agency, in its discretion, believes it is appropriate.

3. Health fraud enforcement often involves several agencies or officials at both the Federal and State government levels. At the outset of a case, the involved State officials may be commissioned by FDA or under contract to FDA and, therefore, have access to relevant confidential commercial information in FDA records. However, as evidence is gathered and the case develops, a point is reached when enforcement strategy must be discussed with other State government officials, who seldom hold FDA commissions or are under contract. Under the current regulations, these State government officials may not have access to pertinent information from FDA records, including information about the identity of investigational products or distribution data that may bear on the case. In such circumstances, the process of investigating and prosecuting the case is frustrated and delayed. That delay and the resulting harm to specific investigations are aggravated in cases where a perpetrator may be operating in several States.

In one particular case, a State official responsible for issuing and revoking medical licenses requested reports covering FDA investigations of health fraud by a physician who was illegally importing and distributing unapproved drugs. The State was initiating a license revocation proceeding. Because the current version of § 20.88 makes disclosure to a noncommissioned or noncontract State employee a public disclosure, the records provided by FDA had to be purged of information vital to the State's revocation case. Consequently, action to protect the public health in this instance was impeded by FDA's inability to disclose nonpublic information to the appropriate State official in a timely manner.

4. Data in FDA's possession about the distribution of an imported product may contain confidential commercial information. Many imported products can be tracked by State officials more

economically and efficiently than by FDA officials, because the tracking can be done in the course of regular State inspectional activities. Under current regulations, FDA's authority to disclose nonpublic information about consignees to State government officials for followup action, such as embargo of violative products, is limited.

A common element of these examples is that joint FDA and State government efforts on significant public health issues, including effective regulatory activities, have been encumbered by existing regulatory restrictions on FDA's ability to exchange confidential commercial information with State governments. The amendment being proposed would facilitate such disclosures and thereby contribute to economy of effort, efficient use of public resources, and enhanced public health protection.

Additionally, FDA believes it should have the ability to disclose proprietary information to State government scientists visiting FDA as part of a joint review or long-term cooperative training effort authorized under section 708 of the act (21 U.S.C. 379), pursuant to the same procedures FDA recently promulgated for visiting foreign scientists. Efficient public administration requires that FDA be able to deal with visiting State government scientists in the same manner as it does with visiting foreign government scientists.

This proposed rule, therefore, would provide, through an amendment to § 20.88, the same mechanisms for exchanges of confidential commercial information between FDA and State government officials as were recently provided for foreign government officials through an amendment to § 20.89. Under the proposed amendment, several conditions must be met prior to FDA's disclosure of such information to State government officials.

First, the State government agency must 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. Second, FDA must make one or more of the following determinations: (1) The sponsor of the product application has provided written authorization for the disclosure; (2) disclosure would be in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or