application of enforcement actions and sanctions will be very important. If FDA cannot easily exchange nonpublic information with State government officials, cooperative efforts may be less effective.

F. Summary of Background

Exchanges of nonpublic information that meet the conditions established in the proposal will facilitate Federal-State uniformity and international harmonization in order to maximize consumer protection and minimize the possibility that unnecessarily disparate measures will be adopted on a particular issue. In order to enhance effective regulatory activities and expeditious review of significant public health issues, FDA has concluded that it needs the ability, in selected circumstances, to disclose confidential commercial information to State government officials, just as it earlier determined that it may be necessary at times to disclose such information to foreign government officials. Furthermore, in order to prepare new regulations or modify existing regulations, issue technical requirements, or undertake a variety of other activities, FDA may need to exchange draft proposals with counterpart State government or foreign government officials in the same way it exchanges similar information with other U.S. government agencies. Federal-State uniformity and international harmonization are facilitated when such exchanges can take place at early stages under circumstances that allow the frank exchange of views among technical experts. FDA's experience over the last decade has convinced the agency that foreign and State government technical and scientific staff perform the same advisory function, in many instances, as other agency employees and that the recommendations of such experts are important to effective decisionmaking.

Of course, any information provided by State or foreign government officials upon which FDA is relying in proposing a new regulation or proposed change in existing regulations would be included in published proposals or final rules in accordance with the Administrative Procedure Act (5 U.S.C. 553). The general public will have ample opportunity to comment on such proposals and their bases at that time. FDA also emphasizes that disclosures to foreign and State counterparts under final regulations based on these proposals would not be a routine occurrence, but would occur only in limited situations.

II. Proposed Amendments

A. The Proposal to Extend to State Government Officials the Recent Regulatory Provisions for Exchanging Confidential Commercial Information With Foreign Government Officials

Proposed § 20.88(d) covers the nonpublic disclosure of certain information that is protected from mandatory public disclosure by exemption 4 of the FOIA, 5 U.S.C. 552(b)(4) to State government officials. Exemption 4 covers two broad categories of information in Federal agency records: Trade secret information, and information that is: (1) Commercial or financial, (2) obtained from a person, and (3) privileged or confidential ("confidential commercial information").

Trade secret information has been defined by the courts as information relating to the making, preparing, compounding, or processing of trade commodities (Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983)). This definition, which requires a "direct relationship" between the trade secret and the productive process, applies to a relatively narrow category of information that coincides with information prohibited from disclosure under section 301(j) of the act (21 U.S.C. 331(j)). FDA recently amended § 20.61 to reflect this definition (59 FR 531, January 5, 1994). That amendment was part of an update of the agency's FOIA regulations to reflect changes that were required by the 1986 amendments to the FOIA and which have already been put into practice by the agency. The amended definition of "trade secret" in part 20 is a restatement of the standard established by Public Citizen Health Research Group, and puts the definition in conformity with applicable case law and with HHS's FOIA regulations. Because FDA's practice has been in accordance with the judicial standards that resulted from Public Citizen Health Research Group and with the definitions established by HHS, the amendment to § 20.61 did not alter the agency's practice in any way or the expectations of the public or regulated industry concerning FDA's treatment of particular types of information.

Nor will the proposed amendment to § 20.88 alter FDA's existing practice with respect to the narrow category of information that can be considered "trade secret." The proposed amendment to § 20.88 expressly excludes the disclosure of information that would fall into the trade secret category to State government officials, without the express authorization of the submitter. The only exception is that State scientists visiting FDA as part of a joint review or long-term training effort authorized under section 708 of the act (21 U.S.C. 379) may, under additional safeguards specified in the rule, be allowed access to such information.

It has been an agency practice to disclose confidential information, including trade secret information, to visiting government scientists insofar as that access is authorized under confidentiality agreements for a training or joint review activity under section 708 of the act and § 20.90. This proposed rule (§ 20.88(d)(1)(ii)(C)) codifies the procedures for providing access to such information in the rule on exchanging information with State government officials rather than continuing this practice under the more general § 20.90 procedures.

The principal focus of this part of the proposed rulemaking is the disclosure to State government officials of the other category of information covered by exemption 4 of the FOIA, "confidential commercial information," including agency-prepared reviews of such information, and records that include such information. Commercial or financial information that a person is required to provide FDA is "confidential" for purposes of exemption 4 if disclosure of the information is likely to: (1) Impair the Government's ability to obtain necessary information in the future or (2) cause substantial harm to the competitive position of the person from whom the information was obtained. (See Critical Mass Energy Project v. NRC, 975 F.2d 871, 877-880 (D.C. Cir. 1992) (en banc), cert. denied, 113 S.Ct. 1579 (1993); National Parks and Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974).) Commercial or financial information that is provided to FDA on a voluntary basis is "confidential" if it is of a kind that the provider would not customarily release to the public. (See Critical Mass Energy Project at 880). The types of information that may be exempt from public disclosure pursuant to this section of the FOIA include: Business sales statistics, customer and supplier lists, research data, profit and loss data, and overhead and operating costs. Under many circumstances, FDA also treats data supporting product approval submissions as confidential commercial information that is entitled to be prohibited from public disclosure. Thus, under the amended regulation, confidential commercial information submitted to the agency that could be disclosed to State governments would