degree of Federal-State cooperation was not contemplated back in 1974 when FDA first issued its public information regulations. New Federal laws enacted since 1974 have also emphasized the importance of Federal-State cooperation. Statutes such as the Prescription Drug Marketing Act of 1987, the Nutrition Labeling and Education Act of 1990, and the Mammography Quality Standards Act of 1992 have created regulatory schemes in which the Federal government establishes programs and standards and States play a major role in operations and enforcement.

This final rule is the second initiative in which FDA has amended its public information regulations to reflect its growing involvement in international activities. In the Federal Register of November 19, 1993 (58 FR 61598), FDA published a final rule amending its regulations governing communications with foreign officials (hereinafter referred to as the 1993 final rule). The 1993 final rule, which is now codified in § 20.89 (21 CFR 20.89), permits FDA, under certain safeguards, to disclose confidential commercial information concerning FDA-regulated products to foreign government officials who perform counterpart functions to FDA ''as part of cooperative law enforcement or regulatory efforts.'' Those safeguards include: (1) A written statement from the foreign government agency establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose such information without the sponsor's written permission or written confirmation from FDA that the information is no longer confidential; and (2) a determination by FDA that the sponsor has provided written authorization for the disclosure, disclosure would be in the interest of public health, or disclosure is to a foreign scientist visiting FDA, on FDA's premises, as part of a joint review or long-term cooperative training effort and other safeguards. Except in the case of foreign scientists working on FDA's premises, the 1993 final rule did not authorize disclosure of trade secret information without written permission from the person that had submitted the trade secret information.

The 1993 final rule led the agency to consider whether the privileges accorded to foreign government representatives should be extended to State and local government officials. Although States carry out relatively few product approval programs, they are significant partners to FDA in such areas as bioresearch monitoring. The agency ultimately decided that there are times when FDA needs to be able to share confidential commercial information with State and local government officials and that, when FDA grants such access, it should be subject to the same restrictions and limitations on disclosure as in cases where FDA grants foreign government officials access to confidential commercial information. Also, cooperative regulatory activities would be enhanced if FDA could provide nonpublic, predecisional documents to State and foreign counterparts.

Consequently, FDA published a proposed rule (60 FR 5530) to amend § 20.88 (21 CFR 20.88) to: (1) Permit the agency to disclose confidential commercial information submitted to FDA or incorporated into FDA-prepared records to State government officials, and (2) disclose to or receive from State government officials nonpublic predecisional documents concerning FDA's or the State agency's regulations, regulatory requirements, or other nonpublic information. In both cases, disclosure would be subject to certain conditions or restrictions, and the information exchanges would not require disclosure to the public. For example, under proposed § 20.88(d), FDA would be authorized to disclose confidential commercial information to State government officials provided that: (1) The State government agency has provided a written statement establishing its authority to protect confidential commercial information and a written commitment not to disclose such information without written permission from FDA or the sponsor of the confidential commercial information; and (2) the agency found that the sponsor has provided written permission for the disclosure, disclosure would be in the interest of the public health, or disclosure would be to a visiting State government scientist on FDA's premises. (See 60 FR 5530 at 5539.)

The proposed rule would also amend § 20.89 to permit FDA to disclose to or receive from foreign government officials nonpublic predecisional documents, provided that certain conditions (such as provision of a written statement establishing the foreign government's authority to protect nonpublic documents from public disclosure) are observed and that certain findings (such as a finding that the exchange is ''reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements'') are made.

II. Analysis of the Comments on the Proposed Rule

FDA received 20 comments on the proposed rule. Ten comments, consisting of letters from nine States and one foreign country, expressed strong support for the proposed rule. In general, these comments indicated that the proposed rule would enhance intergovernmental relations, help eliminate redundant regulatory requirements, permit Federal and State agencies to respond more quickly to potential public health problems, and aid efforts to combat health fraud.

The remaining 10 comments were sent by individual citizens and firms and opposed the proposed rule for the reasons described below. In brief, five comments opposed withholding information from the general public because they saw the proposed rule as undercutting openness in government, whereas the other five comments opposed disclosures because they felt the proposed rule lacked sufficient safeguards to prevent State and foreign government officials from disclosing confidential commercial information or trade secrets to third parties.

A. General Comments

1. Two comments commended FDA for trying to increase intergovernmental cooperation, but argued that, as FDA is not involved in matters of national security or defense, it should not keep any communications from the public. The comments asserted that withholding information from public disclosure would not benefit the public and might diminish public and industry respect for the agency. Similarly, two other comments argued that the proposed rule violated the First Amendment to the U.S. Constitution because it limited the amount of information that the public could examine. The comments stated that the agency had not justified or shown that its interest in denying public access to information exchanged with State and foreign governments exceeds the public's interest in access to that information.

The agency disagrees with the comments. The final rule does not in any way reduce the information in FDA records that the public can examine. Section 20.88(d) permits FDA to provide confidential commercial information to State government officials. Confidential commercial information has historically been exempt from public disclosure requirements, so FDA's providing such information to State government officials while withholding such information from the public will not decrease the amount of information