written commitment not to disclose any such documents without FDA's written confirmation that the information was no longer confidential. One comment would limit disclosures to foreign government officials whose countries ''can reasonably be expected to maintain confidentiality and patent protection at the level acceptable under U.S. intellectual property protection agreements with foreign nations.'' If the agency could not determine whether the foreign country offered ''acceptable'' protection, the comment said that FDA should be required to consult the firm that submitted the confidential commercial information regarding that firm's prior experience with intellectual property protection in the foreign country.

Although this comment pertains to the rulemaking completed in 1993 rather than the present final rule and is outside the scope of this rulemaking, the agency considered similar comments in 1993 when it issued a final rule authorizing the disclosure of confidential commercial information to foreign government officials. The comments asked FDA to restrict disclosures to countries with similar product approval processes or to list foreign governments ''that have been designated as appropriate for the sharing of confidential information.'' (See 58 FR 61598 at 61602.) The agency declined to accept the comments' recommendations, stating that a list of foreign countries would not be useful, repeating that disclosures were subject to certain safeguards, and stating that, ''in every case disclosure is at the discretion of the agency and cannot be automatic for any country.'' Id. The same rationale applies here. FDA will decide, on a case-by-case basis, whether to disclose confidential commercial information to a foreign government and, in most cases, will seek written permission from the party that submitted the confidential commercial information. Given these safeguards, there is no need to establish a list of countries that would protect intellectual property to an ''acceptable'' or ''appropriate'' level. Additionally, because most disclosures would be preceded by written approval from the party submitting the confidential commercial information, there is no need to amend the final rule to require prior consultation with the party that submitted the confidential commercial information.

20. One comment said that proposed § 20.89 would delay public participation in reviewing or commenting on predecisional documents and permit public comment ''only after the agency has more invested in its own viewpoint.''

The agency disagrees with the comment. The agency believes that exchanges of nonpublic, predecisional documents with State and foreign government officials will neither significantly delay public review of such documents nor make any public review less meaningful. FDA will be just as interested in hearing what the public thinks about a proposal, whether or not that proposal was previously shared with a regulatory counterpart. Nor will the agency's obligation to consider or respond to public comments in any way diminish because of this rule.

FDA stresses that the purpose behind exchanging nonpublic, predecisional documents is not to diminish the role of any participant in rulemaking, but to enhance Federal-State uniformity and facilitate global harmonization of regulatory requirements. Although FDA often considers State or foreign regulatory requirements when drafting its own predecisional documents, mutual exchanges between FDA and a State or foreign government will enable refinements in the documents to account for new requirements or developments. The agency believes that, in most cases, the changes that would be made would probably be minor technical adjustments or revisions to a document before publication or release, but, in any event, there should be no significant delay in publication for general review and comment.

The final rule also promotes efficiency during any public review period. Mutual exchanges between FDA and State or foreign governments should result in documents that reflect greater consideration of State or foreign requirements and resources, thereby reducing the possibility that the agency would have to substantially revise or even repropose a proposed regulatory approach due to an inconsistent or conflicting State or foreign requirement identified by comments submitted during a comment period. For example, providing a nonpublic, predecisional document to State governments could alert FDA that its proposed enforcement scheme would overly burden State resources; FDA could then revise the enforcement scheme and publish or release a document that contained the revised enforcement scheme. FDA also reiterates that any document that it publishes in the Federal Register will inform the public of any information from State or foreign government officials that affected the document and provide an opportunity for public comment.

In contrast, if FDA cannot exchange a nonpublic, predecisional documents with State governments, the agency may publish a document proposing an enforcement scheme that places unrealistic burdens on State governments, await comments, publish a second document proposing a revised enforcement scheme, await comments again, and then issue a final document. Under this scenario, public participation might occur earlier, but final action on the initiative would occur later, with attendant delays to the program in question and waste of public resources.

III. Description of the Final Rule

Section 20.88(d) of the final rule authorizes FDA to disclose confidential commercial information submitted to FDA or incorporated into FDA-prepared records to State government officials as part of cooperative law enforcement or regulatory efforts, provided that: (1) The State government agency has provided a written statement establishing its authority to protect the information from public disclosure and has provided 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) FDA has determined that the sponsor has consented, in writing, to disclosure, disclosure would be in the interest of public health, or disclosure would be to a visiting State scientist, subject to certain additional conditions (such as a written assurance that the visiting State scientist has no financial interest in the regulated industry that would preclude him or her from participating in the matter under review). Information exchanged under § 20.88(d) would not be available to the public.

Sections 20.88(e) and 20.89(d) permit the agency to disclose or to receive nonpublic, predecisional documents to or from State or foreign government officials as part of efforts to improve intergovernmental cooperation and uniformity or to implement intergovernmental agreements. The disclosure or receipt of nonpublic, predecisional documents is subject to two conditions: (1) The State or foreign government agency has provided a written statement establishing its authority to protect nonpublic documents from public disclosure and has provided a written commitment not to disclose such documents without FDA's written confirmation that the information no longer has nonpublic status; and (2) the agency has determined that exchange is reasonably