from a party before disclosing confidential commercial information to State government officials. The comment would have the notice describe the information to be disclosed or provide sufficient detail to permit the party to decide whether to withhold permission for disclosure. The comment would also restrict any permission to disclose confidential commercial information to the specific request.

As stated elsewhere in this document, FDA intends, in most cases, to seek written approval from a party before disclosing confidential commercial information. However, the agency declines to require such written approval in all cases because there are situations, such as enforcement actions, where it would be inappropriate to require written approval prior to disclosure.

The agency does agree, however, that a party's written authorization to disclosure of confidential commercial information is limited to a specific request to disclose information and does not constitute automatic authorization to disclose the information to any subsequent State government official seeking to obtain that information. (See 58 FR 61598 at 61602 (stating that "in general, the sponsor needs to authorize further disclosure of confidential information").)

14. Proposed § 20.88(d)(1)(ii)(A) would authorize disclosure of confidential commercial information if disclosure would be "in the interest of the public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State government being able to exercise its regulatory authority more expeditiously" than FDA. One comment objected to this provision, arguing that it provided "no objective criteria for determining when the disclosure of confidential commercial information would be in the interest of public health." The comment claimed that the agency had not shown the State commissioned officials program to be inadequate, that the provision gave no "clear, objective standards outlining the procedure for allowing disclosure," and that the proposed rule would operate in an arbitrary and capricious fashion.

The agency declines to amend the final rule to provide the "objective criteria" requested by the comment. It would be extremely difficult, if not impossible, to draft objective criteria that would encompass all instances where disclosure of confidential commercial information would be in the interest of public health, and any "objective" regulatory criteria would invite parties to dispute the applicability of a particular criterion instead of examining public health concerns and would prevent the final rule from operating in a flexible manner.

FDA further notes that the phrase "interest of public health" is modified by two criteria. Under §20.88(d)(1)(ii)(B), disclosure would be in the interest of public health: (1) By reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation; or (2) by reason of the State government being able to exercise its regulatory authority more expeditiously than FDA. Thus, § 20.88(d)(1)(ii)(B) contemplates disclosures in the interest of public health if a State government possesses information about a product or an investigation or can exercise regulatory authority in a particular situation more quickly than FDA; the provision does not permit unconditional or unrestricted exchanges of confidential commercial information. As stated in the preamble to the proposed rule, disclosures to State governments will not be a routine occurrence, but would occur only in limited situations and on a case-by-case basis. (See 60 FR 5530 at 5535.)

As for the comment claiming that the agency had not shown the commissioned officials program to be inadequate, the preamble to the proposed rule described the commissioning process for State government officials and explained why commissioned officials might not always be the best or most appropriate persons to receive the types of confidential commercial information or nonpublic, predecisional documents contemplated by the rule. In brief, section 702(a) of the act (21 U.S.C. 372(a)) authorizes FDA to conduct examinations and investigations through employees of the Department of Health and Human Services (HHS) or through any health, food, or drug officer or employee of any State, territory, or political subdivision commissioned as an officer of HHS. (See 60 FR 5530 at 5531.) State or local government officials commissioned under this program have a status with respect to disclosure of FDA records that permits the commissioned official to review confidential investigative files and proposed policy statements that are normally restricted to Federal employees. Thus, FDA can solicit advice from these commissioned officials without public disclosure.

The commissioning process, however, is too cumbersome to be practical in the

situations that led FDA to issue the proposed rule. A commissioned official is authorized to perform one or more of the following functions: (1) Conduct examinations, inspections, and investigations under the act; (2) collect and obtain samples; (3) copy and verify records; and (4) receive and review official FDA documents. (See Regulatory Procedures Manual, chapter 3 (regarding commissioning State and local officials).) A commissioned official is only authorized to review FDA documents that fall within the scope of his or her commission; the official may not necessarily have authorized access to all the information that the agency may need to convey to the State.

Yet, even if commissioning a State government official would enable an official to review FDA documents, such authority would not eliminate the need for the final rule. Commissioning a State government official does not confer any protection to documents supplied by a State government to FDA, whereas § 20.88(e) authorizes the agency to receive nonpublic, predecisional documents from State government officials and to protect those documents from public disclosure. Similar provisions in documents provided to FDA by foreign government officials are set forth in § 20.89(d). If information exchanges are to be valuable and meaningful, the agency must be able to protect State or foreign government documents that it receives, as well as the documents that it sends, and the final rule provides such protection to information that FDA receives.

Additionally, as stated in the preamble to the proposed rule, the commissioning process cannot be easily adapted for situations requiring rapid exchange of information. (See 60 FR 5530 at 5532.) The process involves identifying suitable candidates (and often requires commissioning the candidates' supervisors or State agency heads as well), reviewing the candidates' qualifications, conducting background checks (if necessary), issuing certificates and credentials, and accounting for credentials on a periodic basis. These procedures, even if they were as streamlined as possible, might be both impractical and unnecessary in situations where rapid information exchanges are necessary. Consequently, the agency believes that the final rule gives FDA needed authority to exchange information both quickly and efficiently in situations when reliance on commissioned officials would prove impractical.

15. Two comments would amend proposed § 20.88(d)(1)(ii)(C) to add new requirements to deter unauthorized