disclosures of information. The comments would require visiting State scientists to confirm that they are not employees, consultants, or persons that have any professional relationship with a drug manufacturer and to provide a written commitment not to release or disclose information without approval from FDA and the party submitting the confidential commercial information. The comments would not permit FDA to authorize disclosures unilaterally.

FDA declines to revise the final rule as suggested by the comments. Section 20.88(d)(1)(ii)(C) already contains sufficient safeguards that accomplish the same purpose as those suggested by the comments. For example, the final rule requires a visiting State government scientist to provide a written assurance that he or she ''has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the individual were subject to the conflict of interest rules applicable to the Food and Drug Administration advisory committee members under 21 CFR 14.80(b)(1).'' Under § 14.80(b)(1), advisory committee members are subject to Federal conflict of interest laws and regulations. A visiting State government scientist, therefore, could not truthfully provide the written assurance required under § 20.88(d)(1)(ii)(C) if he or she were an employee or consultant of a drug manufacturer.

FDA also declines to amend the final rule to prevent FDA from authorizing disclosure of confidential commercial information or trade secrets to a visiting State government scientist. Section 20.88(d)(1)(ii)(C) authorizes disclosure to a visiting State government scientist if, among other things: (1) The visiting State government scientist signs a written commitment to protect the confidentiality of the information; (2) the visiting State government scientist provides written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in review of the matter if the visiting State government scientist were subject to FDA's conflict of interest rules; and (3) FDA retains physical control over the information. The agency believes that these safeguards provide sufficient protection to confidential commercial and trade secret information in FDA's possession. The agency further notes that a similar regulation has existed for visiting foreign government scientists since 1993, and the agency has not experienced any difficulties or problems with confidential commercial or trade secret information disclosed to visiting foreign government scientists.

16. One comment said that firms that submitted confidential commercial information should have the opportunity to purge ''highly confidential'' information before disclosure to State government officials. The comment explained that this would enable firms to discuss why FDA should not release certain information to a State government official.

The agency wishes to reassure regulated firms about its concerns for proprietary information, but declines to accept the comment's suggestion. While FDA intends, in most cases, to seek a firm's approval before disclosing confidential commercial information, there are situations where it would be inappropriate to permit firms to purge information before its release to State government officials. For example, if confidential commercial information in a marketing application indicated that a firm might have engaged in fraud or misrepresentation that violated both State and Federal laws, the agency might want to notify its State government counterparts. Permitting a firm to purge that information before its release to a State government official would defeat any State regulatory action. Consequently, the agency declines to amend the final rule as suggested by the comment.

C. Section 20.89—Communications With Foreign Government Officials

17. One comment from a foreign government official supported proposed § 20.89(d) but asked whether FDA would protect the confidentiality of nonpublic, predecisional documents provided by a foreign government.

Section 20.89(d) authorizes the agency to disclose and to receive nonpublic, predecisional documents to or from foreign government officials. Under § 20.89(d)(2), such documents would not be made available to all members of the public. Thus, FDA would maintain the confidentiality of nonpublic, predecisional documents supplied by a foreign government official. The basis for this position is explained in detail in the preamble to the proposed rule (60 FR 5530 at 5536 and 5538).

18. Four comments suggested that FDA either permit firms that submitted the confidential commercial information to purge those records before their release or to decide whether release should occur, or provide summaries to firms regarding the information disclosed to the foreign government.

The agency addressed similar comments when it issued the 1993 final rule permitting FDA to disclose confidential commercial information to foreign government officials. The preamble to the 1993 final rule stated that: (1) Any disclosure would be on a case-by-case basis under assurances of continuing confidentiality; (2) the agency will, in most circumstances, seek written authorization from the party submitting the confidential commercial information to permit disclosure; and (3) there are situations where it would be inappropriate to require consent from a party that submitted confidential commercial information. (See 58 FR 61598 at 61601.)

The same rationale applies here. FDA reiterates that the final rule authorizes disclosure only to those governments that have provided written assurances that they have the authority to protect confidential commercial information and nonpublic, predecisional documents from public disclosure and that they will not disclose such documents or information without the written permission of the sponsor or written confirmation from FDA that the information or documents are no longer confidential. Additionally, in most cases, FDA intends to seek written consent from the party that submitted the confidential commercial information before disclosing that information. To permit parties to purge information would lessen the utility of any information provided to a State or foreign government and invite such governments to withhold information themselves.

Requiring FDA to give parties summaries of information disclosed to a State or foreign government would also be inappropriate or unnecessary. For example, if a State or foreign government were considering whether to take action against a particular product, requiring FDA to provide a summary to the product's manufacturer would alert a violative firm of the potential enforcement action. In an action to help a government identify fraudulent goods, the agency might wish to provide confidential commercial information that would help distinguish legitimate products from fraudulent ones; in such a scenario, providing a summary to the product's manufacturer would be worthless because the manufacturer would already know the information that was the basis of the summary. Thus, the agency declines to accept the comments' suggestions.

19. Proposed § 20.89(d)(1)(i) would require, as a condition to authorizing disclosure of confidential commercial information to a foreign government official, a written statement from the foreign government establishing its authority to protect nonpublic documents from public disclosure and a