foreign governments, to allegations of inappropriate disclosures by their officials.

Furthermore, when FDA issued the 1993 final rule authorizing disclosure of confidential commercial information to foreign government officials, the agency expressly stated that it would cease cooperative ventures with any government that failed to honor its written commitment to preserve the confidentiality of the information provided by FDA. (See 58 FR 61598 at 61603.) The agency will expand this policy to include State governments. FDA's extensive experience sharing nonpublic investigative records with State government officials indicates that unauthorized disclosures are unlikely to occur and that any State employee misconduct will be expeditiously handled in order to preserve cooperative efforts between FDA and State governments.

Moreover, after issuing the 1993 final rule, FDA established internal procedures and model confidentiality agreements for disclosures to foreign government officials. These procedures will be expanded to apply to State government officials.

The agency also notes that, contrary to the comments' belief that firms and individuals have no recourse if a foreign government official makes an unauthorized disclosure of confidential commercial information, Federal law does provide an avenue for relief. Under section 301 of the Trade Act of 1974 as amended, the United States Trade Representative is authorized to take appropriate action against any act, policy, or practice of a foreign government that "is unjustifiable and burdens or restricts United States commerce." (See 19 U.S.C. 2411.) Such actions can be initiated by a petition to the United States Trade Representative. (See 19 U.S.C. 2412.) Additionally, as previously noted, FDA will not exchange information with any foreign government that does not honor its commitment to protect confidential commercial information. FDA believes that the value foreign governments place on the continuing ability to exchange information will also help assure that foreign government officials respect the confidentiality of information that they

8. Three comments suggested adding additional safeguards to proposed §§ 20.88 and 20.89 to decrease the likelihood that unauthorized disclosures of confidential commercial information would occur. In brief, these comments would require State and foreign governments to provide written assurances that individuals who would

have access to the confidential commercial information: (1) Will not be employees, consultants, or persons who have a professional relationship with a drug manufacturer; and (2) will be subject to a confidentiality agreement and/or appropriate laws and regulations prohibiting them from disclosing any information. These comments also would require both FDA and the firm that had submitted the confidential commercial information to FDA to consent, in writing, to any release or disclosure by the State or foreign government.

Under § 20.88(d)(1)(i), a State government agency must provide a written statement establishing its authority to protect confidential commercial information from public disclosure. FDA will supplement this requirement with guidance to States on conflicts of interest and prohibitions

against further disclosure.

FDA declines to amend the final rule to require the agency and the party submitting the confidential commercial information to consent to any release or disclosure by the State or foreign government. This final rule and the 1993 final rule governing disclosures of confidential commercial information to foreign government officials already provide for written consent by the party submitting the confidential commercial information (see § 20.88(d)(1)(i); see also $\S 20.89(c)(1)(i)$ or written permission from FDA before the State or foreign government can make any disclosure. Thus, these rules already would require a State or foreign government to obtain written authorization from the party that submitted the confidential commercial information, or written confirmation from FDA that the information was no longer confidential. The comments' suggested changes, therefore, are unnecessary.

As for disclosures to foreign government officials, since amending § 20.89 in 1993 to allow FDA to disclose confidential commercial information to foreign government officials, the agency has not received any reports of unauthorized disclosures by foreign government officials. The agency acknowledges that, in some cases, firms have requested additional safeguards, similar to those mentioned in the comments, and that the foreign government officials have consented to such additional safeguards. However, FDA's experience under § 20.89 does not indicate that such additional safeguards are necessary.

9. One comment would expand §§ 20.88 and 20.89 so that they applied to State and foreign government officials and "all agents contracted by them for

any part of the review and approval processes involving confidential and trade secret information." The comment would also have State and foreign government officials and agents subject to the same confidentiality restrictions as FDA employees.

The agency agrees with the comment and has amended §§ 20.88(e)(3) and 20.89(d)(3) so that references to State or foreign government officials are understood to include agents contracted by those officials.

10. The agency, on its own initiative, has amended §§ 20.88(e) and 20.89(d) to permit the Deputy Commissioner for Policy to authorize disclosures of nonpublic, predecisional documents to State or foreign government officials. The Deputy Commissioner for Policy is authorized, under 21 CFR 5.20(f), to perform any of the functions of the Commissioner of Food and Drugs with respect to the issuance of notices, proposed rules, and final rules.

11. FDA, on its own initiative, has also amended the authority citation to include a reference to the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401-1403). FDA has taken this action because that statute provides for cooperative agreements between FDA and foreign governments and exchanges of certain information between FDA and States.

B. Section 20.88—Communications With State and Local Government Officials

12. Proposed § 20.88(d)(1)(i) would require, as a condition of authorizing disclosure of confidential commercial information to a State government official, a written statement from the State government agency "establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information' without the sponsor's written permission or FDA's written confirmation that the information was no longer confidential. One comment would require that State agencies provide written assurance that, notwithstanding their own State laws, the State agency would protect any confidential commercial information that it received "in accordance with Federal law and FDA regulations.'

FDA sees no need to amend the final rule as suggested by the comment. FDA would not disclose confidential commercial information to a State government official unless State laws allow adequate protection of that information.

13. One comment would require FDA to notify and to obtain written consent