whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to State government officials as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes one or more of the following determinations:

(A) The sponsor of the product application has provided written authorization for the disclosure;

(B) Disclosure would be in the interest of 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 the Food and

Drug Administration; or

(Č) The disclosure is to a State government scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the act, the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting State government scientist to sign a written commitment to protect the confidentiality of the information, and the visiting State government scientist provides 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 § 14.80(b)(1) of this chapter. Subject to all the foregoing conditions, a visiting State government scientist may have access to trade secret information, entitled to protection under section 301(j) of the act, in those cases where such disclosures would be

a necessary part of the joint review or training.

(2) Except as provided under paragraph (d)(1)(ii)(C) of this section, this provision does not authorize the disclosure to State government officials of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the act, unless pursuant to an express written authorization provided by the submitter of the information.

(3) Any disclosure under this section of information submitted to the Food and Drug Administration or incorporated into agency-prepared records does not invoke the rule established in § 20.21 that such records shall be made available to all members

of the public.

(e)(1) The Commissioner of the Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a State government agency of nonpublic predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect such nonpublic documents from public disclosure and a written commitment not to disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

(3) For purposes of this paragraph, the term "official of a State government agency" includes an employee of an organization of State officials having responsibility to facilitate harmonization of State standards and

requirements in FDA's areas of responsibility. For such an official, the statement and commitment required by paragraph (e)(1)(i) of this section shall be provided by both the organization and the individual.

3. Section 20.89 is amended by adding new paragraph (d) to read as follows:

§ 20.89 Communication with foreign government officials.

* * * * *

- (d)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:
- (i) The foreign government agency has provided both a written statement establishing its authority to protect such nonpublic documents from public disclosure and a written commitment not to disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and
- (ii) The Commissioner of Food and Drugs or the Commissioner's designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.
- (2) Any exchange under this section of nonpublic documents does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.
- (3) For purposes of this paragraph, the term "official of a foreign government agency" includes, an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility. For such an official, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.