(ii) The Deputy Commissioner for Policy or the Deputy Commissioner for Policy's designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established at § 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, but is not limited to, an agent contracted by the State government, and 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 officials, 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 Communications with foreign government officials.

* * * * *

- (d)(1) The Deputy Commissioner for Policy, or any other officer or employee of the Food and Drug Administration whom the Deputy Commissioner for Policy 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 Deputy Commissioner for Policy or the Deputy Commissioner for Policy'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, but is not limited to, an agent contracted by the foreign government, and an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility. For such officials, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.

Dated: November 30, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
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