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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES

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Subpart E\_Limitations on Exemptions

Sec. 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in Sec. 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to Sec. Sec. 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in Sec. 20.21 that such records shall be made available for disclosure to all members of the public.

(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 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

(C) 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 Federal Food, Drug, and Cosmetic Act (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 Sec. 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 Sec. 20.21 that such records shall be made available to all members of the public.

(e)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their 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 the authority to protect such nonpublic documents from public disclosure and will not 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 Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their 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 Sec. 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

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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.

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