

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 20**

[Docket No. 94N-0308]

Public Information; Communications With State and Foreign Government Officials**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing communications with State and foreign government officials. This final rule permits FDA to receive and to disclose nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to State government officials and to receive or to disclose draft proposed rules and other nonpublic, predecisional documents concerning regulatory requirements or activities to State or foreign government officials. In both cases, disclosures to or by State or foreign government officials would not require FDA to make the information or documents available to the public. This action is necessary to enhance cooperation in regulatory activities, to eliminate unwarranted contradictory regulatory requirements, and to minimize redundant application of similar requirements.

EFFECTIVE DATE: January 8, 1996.**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.**SUPPLEMENTARY INFORMATION:****I. Background**

In the Federal Register of January 27, 1995 (60 FR 5530), FDA published a proposed rule that would enable FDA to disclose to and receive from State government officials confidential commercial information without being compelled to make that information available to the general public. The proposed rule would also enable the agency to share and to receive nonpublic documents, such as draft rules, with State and foreign government officials. Exchanges of information, including nonpublic information, would enhance Federal-State cooperation in regulatory activities, help eliminate unwarranted contradictory regulatory requirements, and minimize redundant application of

similar requirements by domestic and foreign bodies.

The preamble to the proposed rule described the statutory and regulatory provisions that had governed FDA's communications with State and foreign government officials. Generally, FDA has always possessed both statutory and regulatory authority to withhold some information from public disclosure. For example, the Freedom of Information Act (the FOIA) (5 U.S.C. 552) establishes categories of information that are exempt from public disclosure. Such categories of information relevant to FDA records include:

1. Trade secret and confidential commercial information to protect intellectual property rights and research incentives (5 U.S.C. 552(b)(4));
2. Predecisional documents to protect the deliberative process (5 U.S.C. 552(b)(5));
3. Information whose disclosure might invade personal privacy (5 U.S.C. 552(b)(6)); and
4. Investigatory files compiled for law enforcement purposes to protect investigations into violations of the statutes and regulations FDA enforces (5 U.S.C. 552(b)(7)).

In 1974, FDA issued regulations implementing the FOIA and other laws (such as the Trade Secrets Act (18 U.S.C. 1905) and section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(j)) that affect public access to government records and information. These regulations included a provision, now codified in § 20.21 (21 CFR 20.21), stating that any record that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public. When FDA issued § 20.21 in 1974, it expressly declined to make an exception for records disclosed to foreign governments, stating that:

The Commissioner concludes that the same rules will apply with respect to disclosure of [safety and effectiveness information] to foreign governments as apply to disclosure to the public. This will permit the Food and Drug Administration to provide full summaries of all safety and effectiveness data for all approved [new drug applications (NDA's)] and selected summaries for [investigational new drug applications (IND's)] and pending NDA's of which the existence of an IND has been publicly disclosed or acknowledged. The Commissioner concludes that this will adequately satisfy the need for international exchange of important regulatory information of this type. (See 39 FR 44602 at 44636 and 44637, December 24, 1974.)

However, since 1974, the regulatory environment has changed significantly. Increased international commerce and

diminishing governmental resources have prompted public health regulatory agencies, as well as the industries they regulate, to make efforts to enhance the effectiveness and efficiency of their regulatory efforts. Public health regulatory agencies have engaged in activities to harmonize regulatory requirements, minimize duplicative regulations, and cooperate in joint scientific, regulatory, and enforcement endeavors.

For example, FDA is active in a program known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industry Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, FDA, and the Pharmaceutical Research and Manufacturers of America. In addition, the ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each organizing body and IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area. The ICH expert working groups prepare guidelines on a variety of drug safety, efficacy, and quality matters, and FDA publishes these guidelines in the Federal Register.

Simultaneously, FDA's interaction with State agencies has become more important, particularly as Federal and State authorities have shared responsibilities in certain programs and new authorities have been added. For example, FDA and other Federal and State agencies regulate narcotic treatment program clinics. When new treatments become available, FDA must issue or amend its regulations regarding the new treatment's use and any special conditions on the treatment programs themselves. Yet, State government agencies may share responsibility for ensuring that the treatment programs are licensed and operate in accordance with the law and regulations. The current

degree of Federal-State cooperation was not contemplated back in 1974 when FDA first issued its public information regulations. New Federal laws enacted since 1974 have also emphasized the importance of Federal-State cooperation. Statutes such as the Prescription Drug Marketing Act of 1987, the Nutrition Labeling and Education Act of 1990, and the Mammography Quality Standards Act of 1992 have created regulatory schemes in which the Federal government establishes programs and standards and States play a major role in operations and enforcement.

This final rule is the second initiative in which FDA has amended its public information regulations to reflect its growing involvement in international activities. In the Federal Register of November 19, 1993 (58 FR 61598), FDA published a final rule amending its regulations governing communications with foreign officials (hereinafter referred to as the 1993 final rule). The 1993 final rule, which is now codified in § 20.89 (21 CFR 20.89), permits FDA, under certain safeguards, to disclose confidential commercial information concerning FDA-regulated products to foreign government officials who perform counterpart functions to FDA "as part of cooperative law enforcement or regulatory efforts." Those safeguards include: (1) A written statement from the foreign government agency establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose such information without the sponsor's written permission or written confirmation from FDA that the information is no longer confidential; and (2) a determination by FDA that the sponsor has provided written authorization for the disclosure, disclosure would be in the interest of public health, or disclosure is to a foreign scientist visiting FDA, on FDA's premises, as part of a joint review or long-term cooperative training effort and other safeguards. Except in the case of foreign scientists working on FDA's premises, the 1993 final rule did not authorize disclosure of trade secret information without written permission from the person that had submitted the trade secret information.

The 1993 final rule led the agency to consider whether the privileges accorded to foreign government representatives should be extended to State and local government officials. Although States carry out relatively few product approval programs, they are significant partners to FDA in such areas as bioresearch monitoring. The

agency ultimately decided that there are times when FDA needs to be able to share confidential commercial information with State and local government officials and that, when FDA grants such access, it should be subject to the same restrictions and limitations on disclosure as in cases where FDA grants foreign government officials access to confidential commercial information. Also, cooperative regulatory activities would be enhanced if FDA could provide nonpublic, predecisional documents to State and foreign counterparts.

Consequently, FDA published a proposed rule (60 FR 5530) to amend § 20.88 (21 CFR 20.88) to: (1) Permit the agency to disclose confidential commercial information submitted to FDA or incorporated into FDA-prepared records to State government officials, and (2) disclose to or receive from State government officials nonpublic predecisional documents concerning FDA's or the State agency's regulations, regulatory requirements, or other nonpublic information. In both cases, disclosure would be subject to certain conditions or restrictions, and the information exchanges would not require disclosure to the public. For example, under proposed § 20.88(d), FDA would be authorized to disclose confidential commercial information to State government officials provided that: (1) The State government agency has provided a written statement establishing its authority to protect confidential commercial information and a written commitment not to disclose such information without written permission from FDA or the sponsor of the confidential commercial information; and (2) the agency found that the sponsor has provided written permission for the disclosure, disclosure would be in the interest of the public health, or disclosure would be to a visiting State government scientist on FDA's premises. (See 60 FR 5530 at 5539.)

The proposed rule would also amend § 20.89 to permit FDA to disclose to or receive from foreign government officials nonpublic predecisional documents, provided that certain conditions (such as provision of a written statement establishing the foreign government's authority to protect nonpublic documents from public disclosure) are observed and that certain findings (such as a finding that the exchange is "reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements") are made.

II. Analysis of the Comments on the Proposed Rule

FDA received 20 comments on the proposed rule. Ten comments, consisting of letters from nine States and one foreign country, expressed strong support for the proposed rule. In general, these comments indicated that the proposed rule would enhance intergovernmental relations, help eliminate redundant regulatory requirements, permit Federal and State agencies to respond more quickly to potential public health problems, and aid efforts to combat health fraud.

The remaining 10 comments were sent by individual citizens and firms and opposed the proposed rule for the reasons described below. In brief, five comments opposed withholding information from the general public because they saw the proposed rule as undercutting openness in government, whereas the other five comments opposed disclosures because they felt the proposed rule lacked sufficient safeguards to prevent State and foreign government officials from disclosing confidential commercial information or trade secrets to third parties.

A. General Comments

1. Two comments commended FDA for trying to increase intergovernmental cooperation, but argued that, as FDA is not involved in matters of national security or defense, it should not keep any communications from the public. The comments asserted that withholding information from public disclosure would not benefit the public and might diminish public and industry respect for the agency. Similarly, two other comments argued that the proposed rule violated the First Amendment to the U.S. Constitution because it limited the amount of information that the public could examine. The comments stated that the agency had not justified or shown that its interest in denying public access to information exchanged with State and foreign governments exceeds the public's interest in access to that information.

The agency disagrees with the comments. The final rule does not in any way reduce the information in FDA records that the public can examine. Section 20.88(d) permits FDA to provide confidential commercial information to State government officials. Confidential commercial information has historically been exempt from public disclosure requirements, so FDA's providing such information to State government officials while withholding such information from the public will not decrease the amount of information

available to the public. Sections 20.88(e) and 20.89(d) pertain to exchanges of nonpublic, predecisional documents with State and foreign government officials. Historically, FDA has generally withheld these documents from public disclosure as well.

The agency also disagrees with any assertion that the final rule violates the First Amendment. While courts have construed the First Amendment as giving the public access to government proceedings, they have declined to provide access to all government operations. Indeed, as the Supreme Court stated in *Press-Enterprise Co. v. Superior Court of California*, 478 U.S. 1, 9 (1986):

Although many governmental processes operate best under public scrutiny, it takes little imagination to recognize that there are some kinds of government operations that would be totally frustrated if conducted openly.

In the present case, requiring FDA to publicly disclose confidential commercial information and predecisional documents that it provides to or receives from State and foreign governments would frustrate the final rule's fundamental purposes. The final rule is intended to encourage information exchanges between governments by assuring State and foreign governments that the information or documents they receive or provide will not be publicly available. The final rule also reassures those who submit confidential commercial information to FDA or to State or foreign governments that such information will be protected. If public access to confidential commercial information were required whenever FDA exchanged such information with a State or foreign government, as the comments suggest, firms would then be obliged to refuse requests for intergovernmental disclosure by FDA, State governments, or foreign governments or even refuse to submit confidential commercial information in order to protect it.

Additionally, courts have established a two-part test of "experience" and "logic" to determine whether the First Amendment requires the governmental proceeding to be open to the public. The first part, "experience," asks whether the proceeding is one that has historically been open to the public. The second part, "logic," asks whether public access would play a significant, positive role in the governmental process. If the government process passes these tests, then a qualified First Amendment right of public access exists; in other words, the right of public access is not absolute or

unconditional. (See *Press-Enterprise Co.*, 478 U.S. 8 and 9; *United States v. Simone*, 14 F.3d 833, 837-839 (3d Cir. 1994).)

Applying the two-part test to the final rule leads to the conclusion that the First Amendment does not require these exchanges of information to be open to the public. Historically, the agency has always protected confidential commercial information and indicated that predecisional documents prepared by the agency are either not available to the general public or available under limited conditions. (See, e.g., 21 CFR 20.61 and 21 CFR 20.62 (nondisclosure of inter- or intra-agency memoranda or letters); 21 CFR 20.64 (nondisclosure of records or information compiled for law enforcement purposes); 21 CFR 10.80 (establishing conditions for release of draft notices and regulations).)

Additionally, under the second prong, it is questionable whether public access would play a significant, positive role in the governmental process. For example, intergovernmental exchanges of confidential commercial information will enable governments to learn more about specific products and, as a result, to develop better and more efficient regulatory or enforcement actions. At the same time, disclosure of such confidential commercial information to the general public does not further any regulatory process, and in any event, is prohibited by 18 U.S.C. 1905. The law recognizes that public disclosure of confidential commercial information may have a detrimental effect on product development; providing a firm's competitors with access to valuable information may create a disincentive for firms to develop innovations or improve their products or methods. The result would be diminished availability of useful products.

Furthermore, intergovernmental exchanges of nonpublic, predecisional documents may help the agency decide whether a regulatory approach it is considering is appropriate or even necessary. While the agency may, in many cases, make draft documents available to the general public (for example, in the Federal Register of July 24, 1995 (60 FR 37856), FDA published a notice announcing the availability of a draft final rule on medical device good manufacturing practices to members of the public as well as to State and foreign regulators), in other cases, providing public access to predecisional documents during the deliberative process could interfere with that process or create misleading impressions about the agency's intentions.

In some cases, premature public disclosure of draft documents can

unnecessarily complicate regulatory actions and undermine public health and safety. For example, if the agency developed a proposal on a particular form of tamper evident packaging, such information could be helpful to other foreign governments. However, premature disclosure of that same information could ultimately prove harmful to the general public if its disclosure would enable those who tamper with products to alter their methods in order to evade detection or to defeat the proposed solution.

FDA further emphasizes that, as stated in the preamble to the proposed rule, if any State or foreign government official provides information that the agency wishes to rely on in its published proposals or the administrative record, the agency will include that information unless inclusion would harm private or governmental interests (see 60 FR 5530 at 5538). When a proposed rule is published, therefore, the general public would be fully informed and have an opportunity to comment on the substance of any advice from State or foreign officials that FDA incorporated into the proposed rule.

The agency reiterates that nonpublic exchanges of information with State and foreign government officials will not be a routine occurrence and that FDA does not intend to prohibit public disclosure of information received from State and foreign government officials if such information can be disclosed without harm to any private or governmental interests.

More importantly, the agency believes that the final rule will result in significant public benefits because the final rule facilitates FDA's access to information and expertise within State and foreign governments and should result in better regulatory proposals and actions. For example, if FDA and a State are considering whether to issue proposed regulations on the same or similar subjects, exchanging nonpublic, predecisional documents might lead both parties to reexamine, modify, or harmonize their proposed regulatory strategy. Preventing the issuance of redundant or unnecessary regulations should benefit the public and the affected industries.

2. One comment claimed that the proposed rule violated the Tenth Amendment to the Constitution. The Tenth Amendment states that, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." The comment argued that the proposed rule violated the Tenth

Amendment because citizens had not yielded to the Federal government their "rights of access to the information generated by our public servants."

The agency disagrees with the comment. The final rule concerns FDA's ability to exchange certain confidential commercial information or nonpublic, predecisional documents with State or foreign government officials. Thus, the final rule pertains to information exchange and access to FDA records and implements Federal authority without impairing State or popular power. Indeed, the final rule can strengthen States' regulatory roles.

3. Two comments said that the proposed rule violated procedural due process because it would give State and foreign government officials "preferential access" to predecisional documents, such as draft regulations, thereby giving those officials "far greater influence over the deliberative process by imparting selected information and opinion" to FDA.

The agency disagrees with the comments' assertion. As the Supreme Court said in *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976), procedural due process "imposes constraints on governmental decisions which deprive individuals of 'liberty' or property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." However, "[d]ue process, unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances * * * [d]ue process is flexible and calls for such procedural protections as the particular situation demands." Id. p. 334 (citations omitted).

Here, the final rule does not impose any constraints or sanctions nor does it deprive individuals of any liberty or property interest. The final rule does not "deprive" the public of its access to confidential commercial information or predecisional documents because such information has always been protected from disclosure. Neither does the final rule deprive the public of the opportunity to comment on rulemaking. As stated in the preamble to the proposed rule:

* * * any information provided by State or foreign government officials upon which FDA is relying will be included in published proposals. At that time, the general public will be fully informed and have an opportunity to comment on the substance of any advice from foreign or State officials that is incorporated into agency proposals or initiatives.

(See 60 FR 5530 at 5538.) This approach is consistent with due process because "[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a

meaningful manner,'" *Mathews*, 424 U.S. 333 (citations omitted).

Moreover, judicial opinions concerning informal rulemaking have focused on the need to ensure that ex parte contacts do not frustrate judicial review or raise serious questions of fairness. (See *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977), cert. denied 434 U.S. 829, rehearing denied 434 U.S. 988 (1977).) There is no *per se* prohibition on ex parte contacts. (See *Action for Children's Television v. FCC*, 564 F.2d 458, 475 n.28 (D.C. Cir. 1977).)

FDA reiterates that it will include in its published proposals any information provided by State or foreign government officials upon which FDA is relying. The agency will make such information available at the time of publication. Thus, the general public will be fully informed and have an opportunity to comment on the substance of any advice from foreign or State officials that is incorporated into agency proposals or initiatives. FDA believes this is consistent with all applicable legal requirements.

4. Two comments claimed that the proposed rule violated rights of privacy and confidentiality because information supplied to FDA, with the expectation that the information would remain confidential, would be eligible for disclosure to officials outside FDA. The comments noted that non-FDA officials may have interests and obligations that differ from those of FDA, the public, or the regulated industry. The comments said that requiring the State or foreign government to provide a written statement establishing its authority to protect confidential commercial information or nonpublic documents from public disclosure was "wholly inadequate" because State and foreign officials are not subject to FDA's management or control. The comments further asserted that much information given to FDA is unreliable, fraudulent, or defamatory and could be used by outside parties for ulterior purposes and that the proposed rule would dissuade submission of confidential information to FDA and encourage submission of false information.

Four other comments expressed similar objections to the proposed rule, stating that foreign governments might use confidential commercial information to benefit their own industries.

The agency has given serious attention to the concerns expressed in the comments, but disagrees that the safeguards are inadequate. As stated earlier, FDA issued a final rule on November 19, 1993, to permit the agency to disclose confidential

commercial information to foreign government officials, subject to certain conditions and safeguards to protect the confidentiality of the information. Since issuing that final rule, the agency is unaware of any misuse or unauthorized disclosure of confidential commercial information supplied to a foreign government. In almost all cases, disclosure occurred with the knowledge and consent of the company that submitted the confidential commercial information to FDA. Thus, FDA's experience with the 1993 final rule indicates that confidential commercial information provided to a foreign government official remains confidential and is not used to benefit the foreign government's industry.

Furthermore, FDA emphasizes that the decision to share information with a foreign government is discretionary and that the agency will deny a foreign government's request for confidential commercial information if the foreign government officials are unable to assure FDA of their ability to protect the information. FDA will also deny access where there is a lack of scientific data or regulatory expertise to contribute to a product review or laboratory or clinical investigation, unless the foreign government intends to use the information for law enforcement purposes. (See 58 FR 61598 at 61600.) Similar standards will apply to exchanges with State governments and State government officials.

FDA also disagrees with the assertion that parties often submit false information to the agency. Submitting false information to the government is a Federal crime under 18 U.S.C. 1001. Submission of false or misleading reports with respect to medical devices is prohibited under section 301(q)(2) of the act (21 U.S.C. 331(q)(2)). Submission of false information may also lead to debarment under section 306 of the act (21 U.S.C. 335a) or assessment of civil money penalties under section 303(g) or 307 of the act (21 U.S.C. 333(g) or 335b). FDA has taken legal action against parties that have submitted false information to the agency and emphasizes that it will not tolerate the submission of false information to the agency.

5. Two comments asserted that the proposed rule was contrary to congressional intent, as expressed in the FOIA, to provide information to the public. The comments explained that the FOIA's exceptions to disclosure represented a balance between the public's "right to know" and the government's interest in not disclosing certain types of information. Thus, the comments claimed, only Congress can

alter that balance. Another comment claimed that an executive branch agency cannot withhold information from the public, stating that only Congress could authorize such action.

The agency disagrees with the comments. The preamble to the proposed rule considered this issue and explained why the agency believes that the proposed rule is consistent with the FOIA. FOIA (5 U.S.C. 552) is a disclosure statute and its exemptions are intended to be discretionary. As stated earlier, those exemptions establish several categories of information that can be withheld from public disclosure. The categories relevant to FDA include: (a) Trade secret and confidential commercial information to protect intellectual property rights and research incentives (5 U.S.C. 552(b)(4)); (b) predecisional documents to protect the deliberative process (5 U.S.C. 552(b)(5)); (c) information whose disclosure might invade personal privacy (5 U.S.C. 552(b)(6)); and (d) investigatory files compiled for law enforcement purposes to protect investigations (5 U.S.C. 552(b)(7)).

For disclosures of confidential commercial information under § 20.88(d), the preamble to the proposed rule explained that the FOIA protects two broad categories of information from mandatory public disclosure: Trade secret information and "information that is: (1) Commercial or financial, (2) obtained from a person, and (3) privileged or confidential ('confidential commercial information')." (See 60 FR 5530 at 5535.) The preamble to the proposed rule explained that the proposed rule did not alter agency practice with respect to protecting trade secret information (except to permit disclosure to visiting State scientists) and that disclosures of confidential commercial information to State government officials in accordance with the conditions of the proposed rule would not be a public disclosure and would be "authorized" under the Trade Secrets Act. (See 60 FR 5530 at 5536.)

The preamble to the proposed rule also explained why the provisions regarding predecisional documents and other nonpublic information are consistent with the FOIA. The preamble characterized exchanges of nonpublic, predecisional documents between FDA and State and foreign governments as being of the same character as interagency memoranda and letters that are exempt from disclosure under the FOIA. The preamble to the proposed rule stated that:

* * * it is appropriate to assert the deliberative process privilege [to disclosure under the FOIA] in response to requests for public access to certain communications from State and foreign government officials because the same policy reasons that support nondisclosure of deliberative and predecisional memoranda generated by Federal government agencies justify withholding, in many circumstances, the advice and recommendations generated for FDA by State and foreign government counterparts.

The agency's ability to make sound decisions about the development and implementation of public health and harmonization initiatives is enhanced by access to the advice and recommendations of experts in State and foreign governments who are engaged in similar efforts in their own jurisdictions. The agency views this kind of consultation as functionally equivalent to the "intra-" or "interagency" deliberation more commonly protected by exemption 5 of the FOIA. Indeed, it is frequently the case that advice from a State or foreign health official whose responsibilities parallel those of FDA officials concerning the feasibility of a particular technical or harmonization regulation will be as relevant as similar recommendations solicited from employees in other Federal government agencies. (See 60 FR 5530 at 5536 and 5537.) The preamble to the proposed rule noted that courts have applied a "functional" test for assessing the applicability of the exemption for intra- and interagency memoranda and letters and have included "nonagencies" within the exemption. *Id.*

The preamble also noted that in circumstances where advice or information is provided by foreign governments pursuant to international agreements that require confidentiality as a condition of exchange, FDA believes that a record so provided is not necessarily an "agency record" subject to FOIA. *Id.* at 60 FR 5537 through 5538. The agency cited recent court decisions suggesting that FDA could honor requests for confidentiality under these circumstances without contravening public disclosure requirements established by Congress. *Id.*

Thus, the final rule is consistent with the FOIA, and the agency declines to amend the final rule to require public access to documents beyond that required by the FOIA.

6. One comment said that FDA should discuss the proposed rule's potential effects, costs, and implications in a public forum.

FDA believes that notice and comment rulemaking has provided a satisfactory public forum for this issue.

7. Three comments said that FDA cannot ensure that no unauthorized disclosures of confidential commercial information will occur and cannot take

effective action against State or foreign government officials if unauthorized disclosures occur. Two comments added that the agency should describe how it intends to monitor and investigate reports of unauthorized disclosures and take action against those employees making unauthorized disclosures. One comment suggested that FDA establish a mechanism to track such unauthorized disclosures, analyze and report any patterns or trends in unauthorized disclosures, and, if FDA becomes aware of any unauthorized disclosures by State or foreign government officials, notify the company whose confidential commercial information was disclosed and cease information exchanges with the State or foreign government.

FDA cannot guarantee that no unauthorized disclosures of confidential commercial information will ever occur, but it does note that procedures already exist for investigating reports of unauthorized disclosures. In 1994, the agency created the Office of Internal Affairs (OIA). OIA consists of one Special Agent in Charge and a team of Special Agents. These agents are trained criminal investigators and report directly to the Commissioner of Food and Drugs or the Deputy Commissioner/Senior Advisor. FDA described OIA's functions in a notice published in the Federal Register of January 23, 1995 (60 FR 4417 and 4418). In brief, OIA:

- Provides a centralized Agencywide investigative resource for the Commissioner, the Deputy Commissioners, and top Agency management;

- Provides a centralized investigative liaison between FDA and the Office of the Inspector General (OIG);

- Serves as an FDA investigative resource to conduct internal FDA investigations and to support OIG investigations; and

OIA is also responsible for investigating all allegations of misconduct by FDA employees. (See 59 FR 67087, December 28, 1994.) To assist in this task, the office uses a data base to track cases by type of investigation. One investigation type is "Unauthorized Release of Information."

Whenever OIA receives any report of unauthorized disclosures of information, OIA investigates the report and works with the OIG where appropriate. If the investigation suggests that Federal laws were violated, this information is presented to the OIG and may be referred to the Department of Justice for prosecution. These same resources and procedures could be applied, in cooperation with State and

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 receive.

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 § 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

from a party before disclosing confidential commercial information to State government officials. The comment would have the notice describe the information to be disclosed or provide sufficient detail to permit the party to decide whether to withhold permission for disclosure. The comment would also restrict any permission to disclose confidential commercial information to the specific request.

As stated elsewhere in this document, FDA intends, in most cases, to seek written approval from a party before disclosing confidential commercial information. However, the agency declines to require such written approval in all cases because there are situations, such as enforcement actions, where it would be inappropriate to require written approval prior to disclosure.

The agency does agree, however, that a party's written authorization to disclosure of confidential commercial information is limited to a specific request to disclose information and does not constitute automatic authorization to disclose the information to any subsequent State government official seeking to obtain that information. (See 58 FR 61598 at 61602 (stating that "in general, the sponsor needs to authorize further disclosure of confidential information").)

14. Proposed § 20.88(d)(1)(ii)(A) would authorize disclosure of confidential commercial information if disclosure would be "in the interest of the 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 FDA. One comment objected to this provision, arguing that it provided "no objective criteria for determining when the disclosure of confidential commercial information would be in the interest of public health." The comment claimed that the agency had not shown the State commissioned officials program to be inadequate, that the provision gave no "clear, objective standards outlining the procedure for allowing disclosure," and that the proposed rule would operate in an arbitrary and capricious fashion.

The agency declines to amend the final rule to provide the "objective criteria" requested by the comment. It would be extremely difficult, if not impossible, to draft objective criteria that would encompass all instances where disclosure of confidential commercial information would be in the interest of public health, and any

"objective" regulatory criteria would invite parties to dispute the applicability of a particular criterion instead of examining public health concerns and would prevent the final rule from operating in a flexible manner.

FDA further notes that the phrase "interest of public health" is modified by two criteria. Under § 20.88(d)(1)(ii)(B), disclosure would be in the interest of public health: (1) By reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation; or (2) by reason of the State government being able to exercise its regulatory authority more expeditiously than FDA. Thus, § 20.88(d)(1)(ii)(B) contemplates disclosures in the interest of public health if a State government possesses information about a product or an investigation or can exercise regulatory authority in a particular situation more quickly than FDA; the provision does not permit unconditional or unrestricted exchanges of confidential commercial information. As stated in the preamble to the proposed rule, disclosures to State governments will not be a routine occurrence, but would occur only in limited situations and on a case-by-case basis. (See 60 FR 5530 at 5535.)

As for the comment claiming that the agency had not shown the commissioned officials program to be inadequate, the preamble to the proposed rule described the commissioning process for State government officials and explained why commissioned officials might not always be the best or most appropriate persons to receive the types of confidential commercial information or nonpublic, predecisional documents contemplated by the rule. In brief, section 702(a) of the act (21 U.S.C. 372(a)) authorizes FDA to conduct examinations and investigations through employees of the Department of Health and Human Services (HHS) or through any health, food, or drug officer or employee of any State, territory, or political subdivision commissioned as an officer of HHS. (See 60 FR 5530 at 5531.) State or local government officials commissioned under this program have a status with respect to disclosure of FDA records that permits the commissioned official to review confidential investigative files and proposed policy statements that are normally restricted to Federal employees. Thus, FDA can solicit advice from these commissioned officials without public disclosure.

The commissioning process, however, is too cumbersome to be practical in the

situations that led FDA to issue the proposed rule. A commissioned official is authorized to perform one or more of the following functions: (1) Conduct examinations, inspections, and investigations under the act; (2) collect and obtain samples; (3) copy and verify records; and (4) receive and review official FDA documents. (See Regulatory Procedures Manual, chapter 3 (regarding commissioning State and local officials).) A commissioned official is only authorized to review FDA documents that fall within the scope of his or her commission; the official may not necessarily have authorized access to all the information that the agency may need to convey to the State.

Yet, even if commissioning a State government official would enable an official to review FDA documents, such authority would not eliminate the need for the final rule. Commissioning a State government official does not confer any protection to documents supplied by a State government to FDA, whereas § 20.88(e) authorizes the agency to receive nonpublic, predecisional documents from State government officials and to protect those documents from public disclosure. Similar provisions in documents provided to FDA by foreign government officials are set forth in § 20.89(d). If information exchanges are to be valuable and meaningful, the agency must be able to protect State or foreign government documents that it receives, as well as the documents that it sends, and the final rule provides such protection to information that FDA receives.

Additionally, as stated in the preamble to the proposed rule, the commissioning process cannot be easily adapted for situations requiring rapid exchange of information. (See 60 FR 5530 at 5532.) The process involves identifying suitable candidates (and often requires commissioning the candidates' supervisors or State agency heads as well), reviewing the candidates' qualifications, conducting background checks (if necessary), issuing certificates and credentials, and accounting for credentials on a periodic basis. These procedures, even if they were as streamlined as possible, might be both impractical and unnecessary in situations where rapid information exchanges are necessary. Consequently, the agency believes that the final rule gives FDA needed authority to exchange information both quickly and efficiently in situations when reliance on commissioned officials would prove impractical.

15. Two comments would amend proposed § 20.88(d)(1)(ii)(C) to add new requirements to deter unauthorized

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

written commitment not to disclose any such documents without FDA's written confirmation that the information was no longer confidential. One comment would limit disclosures to foreign government officials whose countries "can reasonably be expected to maintain confidentiality and patent protection at the level acceptable under U.S. intellectual property protection agreements with foreign nations." If the agency could not determine whether the foreign country offered "acceptable" protection, the comment said that FDA should be required to consult the firm that submitted the confidential commercial information regarding that firm's prior experience with intellectual property protection in the foreign country.

Although this comment pertains to the rulemaking completed in 1993 rather than the present final rule and is outside the scope of this rulemaking, the agency considered similar comments in 1993 when it issued a final rule authorizing the disclosure of confidential commercial information to foreign government officials. The comments asked FDA to restrict disclosures to countries with similar product approval processes or to list foreign governments "that have been designated as appropriate for the sharing of confidential information." (See 58 FR 61598 at 61602.) The agency declined to accept the comments' recommendations, stating that a list of foreign countries would not be useful, repeating that disclosures were subject to certain safeguards, and stating that, "in every case disclosure is at the discretion of the agency and cannot be automatic for any country." *Id.* The same rationale applies here. FDA will decide, on a case-by-case basis, whether to disclose confidential commercial information to a foreign government and, in most cases, will seek written permission from the party that submitted the confidential commercial information. Given these safeguards, there is no need to establish a list of countries that would protect intellectual property to an "acceptable" or "appropriate" level. Additionally, because most disclosures would be preceded by written approval from the party submitting the confidential commercial information, there is no need to amend the final rule to require prior consultation with the party that submitted the confidential commercial information.

20. One comment said that proposed § 20.89 would delay public participation in reviewing or commenting on predecisional documents and permit public comment "only after the agency

has more invested in its own viewpoint."

The agency disagrees with the comment. The agency believes that exchanges of nonpublic, predecisional documents with State and foreign government officials will neither significantly delay public review of such documents nor make any public review less meaningful. FDA will be just as interested in hearing what the public thinks about a proposal, whether or not that proposal was previously shared with a regulatory counterpart. Nor will the agency's obligation to consider or respond to public comments in any way diminish because of this rule.

FDA stresses that the purpose behind exchanging nonpublic, predecisional documents is not to diminish the role of any participant in rulemaking, but to enhance Federal-State uniformity and facilitate global harmonization of regulatory requirements. Although FDA often considers State or foreign regulatory requirements when drafting its own predecisional documents, mutual exchanges between FDA and a State or foreign government will enable refinements in the documents to account for new requirements or developments. The agency believes that, in most cases, the changes that would be made would probably be minor technical adjustments or revisions to a document before publication or release, but, in any event, there should be no significant delay in publication for general review and comment.

The final rule also promotes efficiency during any public review period. Mutual exchanges between FDA and State or foreign governments should result in documents that reflect greater consideration of State or foreign requirements and resources, thereby reducing the possibility that the agency would have to substantially revise or even repropose a proposed regulatory approach due to an inconsistent or conflicting State or foreign requirement identified by comments submitted during a comment period. For example, providing a nonpublic, predecisional document to State governments could alert FDA that its proposed enforcement scheme would overly burden State resources; FDA could then revise the enforcement scheme and publish or release a document that contained the revised enforcement scheme. FDA also reiterates that any document that it publishes in the Federal Register will inform the public of any information from State or foreign government officials that affected the document and provide an opportunity for public comment.

In contrast, if FDA cannot exchange a nonpublic, predecisional documents with State governments, the agency may publish a document proposing an enforcement scheme that places unrealistic burdens on State governments, await comments, publish a second document proposing a revised enforcement scheme, await comments again, and then issue a final document. Under this scenario, public participation might occur earlier, but final action on the initiative would occur later, with attendant delays to the program in question and waste of public resources.

III. Description of the Final Rule

Section 20.88(d) of the final rule authorizes FDA to disclose confidential commercial information submitted to FDA or incorporated into FDA-prepared records to State government officials as part of cooperative law enforcement or regulatory efforts, provided that: (1) The State government agency has provided a written statement establishing its authority to protect the information from public disclosure and has provided a written commitment not to disclose such information without the sponsor's written permission or written confirmation from FDA that the information is no longer confidential; and (2) FDA has determined that the sponsor has consented, in writing, to disclosure, disclosure would be in the interest of public health, or disclosure would be to a visiting State scientist, subject to certain additional conditions (such as a written assurance that the visiting State scientist has no financial interest in the regulated industry that would preclude him or her from participating in the matter under review). Information exchanged under § 20.88(d) would not be available to the public.

Sections 20.88(e) and 20.89(d) permit the agency to disclose or to receive nonpublic, predecisional documents to or from State or foreign government officials as part of efforts to improve intergovernmental cooperation and uniformity or to implement intergovernmental agreements. The disclosure or receipt of nonpublic, predecisional documents is subject to two conditions: (1) The State or foreign government agency has provided a written statement establishing its authority to protect nonpublic documents from public disclosure and has provided a written commitment not to disclose such documents without FDA's written confirmation that the information no longer has nonpublic status; and (2) the agency has determined that exchange is reasonably

necessary to cooperative regulatory activities or to improve Federal-State uniformity or to facilitate international harmonization of regulatory requirements. Information exchanged under §§ 20.88(e) or 20.89(d) will not be available to the public.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule promotes harmonized regulatory requirements, nationally and internationally, thereby reducing disparate regulatory requirements, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 1401–1403.

2. Section 20.88 is amended by adding new paragraphs (d) and (e) to read as follows:

§ 20.88 Communications with State and local 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 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 § 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 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 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 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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