

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing communications with officials of State and foreign governments. This proposal will permit FDA to disclose to, and receive from, these officials certain nonpublic information without being compelled to disclose the information to the public generally. This proposal addresses the nonpublic exchange of two types of information. First, it allows the disclosure of nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to State government officials. Second, it allows the disclosure of draft proposed rules and other nonpublic predecisional documents concerning regulatory requirements or activities between FDA and either State or foreign government officials. This action is necessary to enhance cooperation in regulatory activities, to eliminate unfounded contradictory regulatory requirements, and to minimize redundant application of similar requirements.

DATES: Written comments by April 27, 1995. FDA is proposing that any final rule that may issue based on this proposal become effective on or before February 27, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Linda R. Horton, International Policy Staff (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2831.

SUPPLEMENTARY INFORMATION:

I. Background

Historically, FDA's communications with State and foreign government officials generally had the same status as communications with any member of the public. Under FDA's rules as they were originally published in 1974, under many circumstances, the

disclosure of agency records by FDA to such government officials constituted disclosure to the public and obligated FDA to make the same records available to the public upon request. As discussed below, however, there have been certain longstanding exceptions to this general rule of uniform access.

FDA is a strong supporter of the public's "right to know" about government actions and public access to official information. There are times, however, when public disclosure of information will undermine other legitimate private rights and government responsibilities. In drafting the Freedom of Information Act (the FOIA) (5 U.S.C. 552), Congress recognized the need for the Federal government to be able to withhold certain categories of information from public disclosure. Examples of such categories of records relevant to FDA 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 the disclosure of which may invade personal privacy (5 U.S.C. 552(b)(6)); and
4. Investigatory files compiled for law enforcement purposes to protect investigations into misconduct (5 U.S.C. 552(b)(7)).

Since 1974, significant changes in the world economy and in the activities of the regulatory agencies of the world's governments have caused FDA to work more closely with other government officials (i.e., local, State, and foreign officials, as well as fellow Federal officials) as professional colleagues in the attempt to find solutions to public health and consumer protection problems.

Increased international commerce and diminished resources for regulation have resulted in efforts by public health regulatory agencies around the globe to enhance the effectiveness and efficiency of their operations. Public health regulatory agencies are protecting the public by harmonizing regulatory requirements; minimizing duplicative regulations; and cooperating in scientific, regulatory, and enforcement activities. Similar factors have demanded enhanced cooperation among all levels of government within the United States. To facilitate these national and international cooperative activities, regulatory agencies, both within the United States and worldwide, have taken steps to increase communications with their counterparts when developing proposed regulations

or formulating important regulatory decisions. These discussions occur not only with respect to FDA-regulated products, but in other areas where cooperation is essential, e.g., aircraft safety, pesticide registration, and nuclear power regulation.

An example of the trend toward increased international information sharing is the 1993 revision to FDA's public information regulations, § 20.89 (21 CFR 20.89), providing that, under specified conditions, FDA may disclose certain nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to foreign government officials without being compelled to disclose the information to the public (58 FR 61598, November 19, 1993). In this document, FDA is proposing a regulation authorizing disclosure of certain nonpublic safety, effectiveness, and quality information to State government officials to parallel the existing regulation for disclosure of this kind of information to foreign government officials. The purpose of this action is to enhance Federal-State cooperation in regulatory activities. In this document, the term "State government officials" can include local officials, because local governments are the legal instruments of the States. However, FDA generally works with State, not local governments, and information exchange with State officials is the more common situation.

FDA is also proposing to exchange (i.e., to disclose, to receive, or to do both) certain nonpublic predecisional documents concerning FDA's or another government's (local, State, or foreign) regulations, requirements, or activities without being compelled to generally disclose the information to the public. The purpose of this action is to facilitate the elimination of unnecessary, contradictory regulatory requirements and to minimize unwarranted, redundant application of similar requirements by multiple domestic and foreign regulatory bodies. Further, this proposed action is intended to enhance FDA's implementation, consistent with the laws it administers, of U.S. policies and obligations resulting from our country's duties under international agreements. FDA believes both changes proposed in this document will enhance consumer protection and increase consumer access to safe, effective, and high quality products that are regulated by FDA.

A. Disclosure of Information to the Public: General Statutory and Regulatory Provisions

FDA's regulations governing public information in part 20 (21 CFR part 20) implement the FOIA, 5 U.S.C. 552, and

other laws that affect public access to government records and information (e.g., 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))). Section 20.21 of FDA's public information regulations states a general rule that any record of the agency that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public. As stated earlier, communications by FDA with State and local government officials and with foreign government officials generally have had the same status as communications with any member of the public.

However, subpart E of part 20 identifies several categories of officials or institutions to whom, under specified limitations, disclosure of certain FDA records may be made without requiring uniform access under § 20.21. These include State and local government officials, under limitations specified in § 20.88, and foreign government officials, under limitations specified in § 20.89. FDA believes that consumer protection will be enhanced if FDA is able to exchange information with other government agencies at an earlier stage than is possible under present rules, and if FDA is able to share with these officials certain categories of information that may not be exchanged under present rules. FDA further believes that protection of intellectual property rights, research incentives, deliberative processes, and similar important needs will not be compromised if certain conditions are met by the recipients of such information.

B. Exchanging Confidential Commercial Information With State and Local Government Officials: Statutory and Regulatory Provisions

Special provisions of the act and FDA regulations permit FDA to treat State and local government officials commissioned by FDA or under contract with FDA essentially as FDA employees. The act authorizes the Secretary of the Department of Health and Human Services (HHS) to conduct examinations and investigations for the purposes of the act through employees of HHS or through any health, food, or drug officer or employee of any State, territory, or political subdivision thereof, commissioned by the Secretary as an officer of HHS (21 U.S.C. 372(a)). This authority has been delegated to FDA (21 CFR 5.10(a)). To facilitate implementation of this provision, § 20.88(a) provides that a State or local government official commissioned by

FDA under 21 U.S.C. 372(a) shall have the same status with respect to disclosure of FDA records as any special government employee under Federal personnel law.

These provisions allow these commissioned officials to review confidential FDA investigative files and proposed policy statements that normally must be restricted to Federal employees. FDA's ability to solicit the advice and tap the expertise of its State and local colleagues without publicly disclosing investigational information outside the agency is a major advantage of the State Commissioning Program. The same rationale supports a broadening of FDA's ability to share information with other State employees.

FDA's current regulations also provide that communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract with FDA shall be subject to the same rules that protect FDA investigatory records from public disclosure. (See § 20.88(b)). Under existing § 20.88, however, communications by FDA with State and local government officials who are neither commissioned by FDA under 21 U.S.C. 372(a), nor under FDA contract, have the same status as communications with any member of the public. Although § 20.88(c)(1) does provide additional protection for investigatory records and trade secrets and confidential commercial information that have been voluntarily disclosed to FDA as part of cooperative law enforcement and regulatory efforts by such noncommissioned and noncontract State and local government officials, the existing regulation does not allow FDA employees to reciprocate with respect to confidential commercial information. FDA may not disclose to noncontract and noncommissioned State officials confidential commercial information submitted to or incorporated into records prepared by FDA. Under current regulations, such disclosure would invoke the uniform access to records requirement in § 20.21, and trigger public availability of this information.

With respect to investigatory records compiled for law enforcement purposes, FDA's rules have long provided the agency with authorization to exchange such investigatory records with State or local government officials who perform counterpart functions to FDA at the State or local levels as part of cooperative law enforcement efforts. (See § 20.88(c)). Such an exchange does not invoke the uniform access rule established by § 20.21. FDA is proposing to expand the categories of information subject to this approach in order to

enhance Federal-State efforts to protect the public health.

C. Exchanging Confidential Commercial Information With Foreign Government Officials: Recent Changes in Regulatory Provisions

When FDA's regulations governing exchange of information with foreign government officials were first codified, national economies worldwide were more independent of one another than now, and regulatory agencies worldwide discharged their responsibilities more independently of one another. Even in 1974, however, the importance of those relationships to the public health and the mission of FDA was clear to the agency. In the preamble to the proposed regulations, the Commissioner of Food and Drugs emphasized "the importance of maintaining good working relationships with counterpart agencies throughout the world both to sound diplomatic relations with foreign nations and to the availability of important new information of regulatory significance. Such cooperation is encouraged by sections 301 and 308 of the Public Health Service Act (42 U.S.C. 241 and 242f). Unless regulatory information can be exchanged without required public disclosure, FDA will lose its sources of important information that are vital to protect the public, and will be unable to disseminate preliminary information when it is first generated within this country in order to help protect the public health throughout the world." (See 39 FR 44602 through 44621, December 24, 1974).

Although the agency at that time declined to implement the suggestions of foreign governments that FDA exchange nonpublic safety and effectiveness data with counterpart officials, the Commissioner's response to those suggestions was at least partially based on the belief that the regulations proposed in 1974 would "adequately satisfy the need for international exchange of important regulatory information of this type." (See 39 FR 44602 at 44636 and 44637).

In the intervening 20 years there have been great changes in the world economy and the working relationships of regulatory agencies around the globe. Experience has shown that efficient and effective regulation can be facilitated by the exchange of confidential commercial information between governments. Cooperation in review of product approval applications is one example of the benefit such exchange can bring to consumers and to industry.

In 1992, FDA proposed to amend § 20.89 to expand the exchange of

information with foreign officials to include certain confidential commercial information, such as studies supporting product approval (57 FR 61598, June 26, 1992). The agency issued a final rule on November 19, 1993 (58 FR 61598). Section 20.89 as amended allows the agency, under specified conditions, to disclose confidential commercial information such as nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to foreign government officials who perform counterpart functions, without compelling the public disclosure of the information. The rule covers confidential commercial information submitted to the agency, or incorporated into agency-prepared records, as part of cooperative law enforcement or regulatory efforts. Under the amended regulation, several conditions must be met before FDA may disclose the information to the foreign government official. The conditions are the same as those proposed below with respect to analogous disclosures to State and local government officials.

One condition requires the foreign government agency to provide a written statement certifying its authority to protect the information from public disclosure and its commitment not to disclose the information without the written permission of the sponsor or written confirmation from FDA that the information no longer has confidential status. FDA requires this written statement to: (1) Include specified language; (2) bear the signature, name, and title of the responsible foreign government official; and (3) be submitted to FDA after the official is informed about the significance the agency attaches to the confidentiality of the information and understands that disclosure by the foreign government could constitute a criminal violation and would seriously jeopardize any further interaction between FDA and the foreign counterpart agency.

As discussed in the preamble to the 1993 final rule, that rulemaking was undertaken because FDA concluded that it needed to revise its public information regulations to disclose to foreign government officials confidential commercial information submitted to FDA or incorporated into agency-prepared records in order to provide clear authority for cooperation in reviews of pending submissions and other important international exchanges of regulatory information. The 1993 final rule facilitates the approval of products that are shown to be safe and effective, expedites the withdrawal of approval of products that are found not to be safe and effective, and enhances

the efficiency of FDA's enforcement efforts, while providing safeguards against public disclosures of proprietary information and conflicts of interest.

D. The Need to Extend to State Government Officials the Recent Changes in Provisions for Exchanging Confidential Commercial Information With Foreign Government Officials

FDA and State agencies work cooperatively and in a complementary manner to protect the nation's public health with regard to FDA-regulated consumer products. While States usually defer to FDA to approve the marketing of FDA-regulated products, some States actively regulate or monitor, within their State and under their own authorities, the clinical trials of some investigational new drugs, biologic products, and medical devices. In addition, most States have active enforcement programs, especially for foods.

FDA needs to be able to exchange information with State or local officials, without being limited to those who are commissioned or are under contract under § 20.88(a) and (b), FDA commissions State government officials, or enters into contracts with State agencies, primarily for the performance of cooperative regulatory work. However, certain cooperative efforts are more dependent on information exchange followed by coordination between Federal and State authorities, rather than on actual work performed by State authorities on behalf of Federal programs. In some regulatory efforts where the need for information exchange is paramount, FDA may be able to rely on FDA commissioned and contract employees in order to share confidential commercial information in the possession of FDA that is necessary to accomplish the agency's public health mission. But, as discussed below, commissioning and contracting, which are essential prerequisites under the current regulation, consume inordinate time and human resources and are not suited to dealing with information exchanges on rapidly developing problems.

Arrangements for issuing commissions are handled by State commission liaison officers located in FDA's regional offices. The commissioning process includes identifying suitable candidates (which often will require that supervisors or State agency heads also be commissioned), reviewing the candidates' qualifications to carry out activities specified in the commission, issuing certificates and credentials, and accounting for the credentials on a

periodic basis. FDA's experience has been that this mechanism is too rigorous, costly, and time-consuming to enable the rapid exchanges of confidential information with State government officials that are essential in public health emergencies and investigations. Furthermore, the State government official who is commissioned, and therefore permitted access to confidential commercial information in FDA's possession, is frequently not the employee who, in any particular case, is best capable of analyzing or evaluating the nonpublic information.

Similarly, contracting projects are not suited for cooperative Federal-State regulatory efforts requiring rapid exchange of information. Contracts are solicited, negotiated, and put in place according to formal U.S. Government contracting procedures; for continuing work, contracts must be renewed annually. In addition to being time-consuming to establish, contracts cannot be relied upon to cover all FDA program areas. The services most commonly procured by FDA through contracts with the States are for establishment inspections, with related collection and analysis of samples, report preparation, and followup activity undertaken by the State agency under its own authority and program. FDA program areas are not covered uniformly across the States, with FDA having contracts in many (but not all) States for food inspections, but in only a few States for drug, biologic product, and medical device inspections.

The following are examples of situations in which the ability to share confidential commercial information with State governments in a less encumbered manner would have allowed more timely review of significant public health issues, or would have enhanced the effectiveness of regulatory activities:

1. FDA and some States acquire information from ongoing clinical investigations of new drugs, biologic products, or medical devices, including unanticipated adverse reaction or device malfunction data, clinical protocols, identities of study sites, and names of clinical investigators. When problems occur that could have an impact upon the safety of study subjects, public health decisions concerning the continuation of the study must be based upon the most complete information possible. This is facilitated by access to records at the study sites, and in certain situations it would be consistent with public health protection for State officials to have access to records that

FDA must evaluate in its review of the problem.

Under the existing regulations, State government officials can share information that they receive or acquire with FDA. However, because information concerning investigational drugs and medical devices is often confidential commercial information, FDA cannot reciprocate, unless the State officials are commissioned or under contract for law enforcement purposes. As explained above, the processes for issuing commissions to State government officials or placing them under contract are so cumbersome and time-consuming as to impede joint Federal-State efforts on clinical trials in progress that require a two-way exchange of relevant information. Such restrictions on the exchange of this information can hinder decisionmaking, for both FDA and State governments, where timeliness is important to protecting public health.

Further, State governments, on occasion, have not had ready access to information about pending FDA regulatory actions concerning clinical trials in progress that may involve health care institutions or individuals which operate under State licenses, permits, or registrations. In such circumstances, the current impediments to full-information exchanges thwart effective, coordinated regulatory solutions to public health problems. For example, in the case of Narcotic Treatment Programs (NTP's), FDA coordinates actions with the State agencies charged with regulating these types of clinics. Such coordination is essential because if FDA plans enforcement action that would close a program, the assistance of the State agencies is necessary to minimize disruption to the treatment of patients. The rapid exchange of nonpublic information can also enhance protection of the public health when a State has broad authority to require an unsafe or violative establishment within its borders to cease operations.

2. Both FDA and State agencies have responsibilities for Institutional Review Boards (IRB's), which are the boards or committees formally designated by institutions to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving use in human subjects of FDA-regulated products (21 CFR § 56.102(g)). In the case of noncompliant IRB's, FDA regulations allow the agency to notify relevant State and Federal regulatory agencies and other parties with a direct interest about any action FDA may take against the IRB or its parent institution (21 CFR 56.120). In

some instances, State action against violations may be preferable to Federal action, or a State may have authority to expeditiously revoke the license of a program or clinic operating under that violative IRB. However, State officials may need access to confidential information about the protocol or investigational product, including nonpublic confidential commercial information contained in IND's and NDA's, in order to take effective action. This proposed rule would permit FDA to share such information, where the agency, in its discretion, believes it is appropriate.

3. Health fraud enforcement often involves several agencies or officials at both the Federal and State government levels. At the outset of a case, the involved State officials may be commissioned by FDA or under contract to FDA and, therefore, have access to relevant confidential commercial information in FDA records. However, as evidence is gathered and the case develops, a point is reached when enforcement strategy must be discussed with other State government officials, who seldom hold FDA commissions or are under contract. Under the current regulations, these State government officials may not have access to pertinent information from FDA records, including information about the identity of investigational products or distribution data that may bear on the case. In such circumstances, the process of investigating and prosecuting the case is frustrated and delayed. That delay and the resulting harm to specific investigations are aggravated in cases where a perpetrator may be operating in several States.

In one particular case, a State official responsible for issuing and revoking medical licenses requested reports covering FDA investigations of health fraud by a physician who was illegally importing and distributing unapproved drugs. The State was initiating a license revocation proceeding. Because the current version of § 20.88 makes disclosure to a noncommissioned or noncontract State employee a public disclosure, the records provided by FDA had to be purged of information vital to the State's revocation case. Consequently, action to protect the public health in this instance was impeded by FDA's inability to disclose nonpublic information to the appropriate State official in a timely manner.

4. Data in FDA's possession about the distribution of an imported product may contain confidential commercial information. Many imported products can be tracked by State officials more

economically and efficiently than by FDA officials, because the tracking can be done in the course of regular State inspectional activities. Under current regulations, FDA's authority to disclose nonpublic information about consignees to State government officials for followup action, such as embargo of violative products, is limited.

A common element of these examples is that joint FDA and State government efforts on significant public health issues, including effective regulatory activities, have been encumbered by existing regulatory restrictions on FDA's ability to exchange confidential commercial information with State governments. The amendment being proposed would facilitate such disclosures and thereby contribute to economy of effort, efficient use of public resources, and enhanced public health protection.

Additionally, FDA believes it should have the ability to disclose proprietary information to State government scientists visiting FDA as part of a joint review or long-term cooperative training effort authorized under section 708 of the act (21 U.S.C. 379), pursuant to the same procedures FDA recently promulgated for visiting foreign scientists. Efficient public administration requires that FDA be able to deal with visiting State government scientists in the same manner as it does with visiting foreign government scientists.

This proposed rule, therefore, would provide, through an amendment to § 20.88, the same mechanisms for exchanges of confidential commercial information between FDA and State government officials as were recently provided for foreign government officials through an amendment to § 20.89. Under the proposed amendment, several conditions must be met prior to FDA's disclosure of such information to State government officials.

First, the State government agency must provide a written statement certifying its authority to protect the information from public disclosure and its commitment not to disclose the information without the written permission of the sponsor or written confirmation from FDA that the information no longer has confidential status. Second, FDA must make one or more of the following determinations: (1) The sponsor of the product application has provided written authorization for the disclosure; (2) 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 (3) the disclosure is to a State government scientist visiting FDA on the agency's premises as part of a joint review or cooperative training effort, and FDA (a) retains physical control over the information, (b) requires a written commitment to protect the confidentiality of the information, and (c) implements specific conflicts-of-interest safeguards.

E. Cooperation and Harmonization Needs for Exchanging Nonpublic Predecisional Documents and Other Nonpublic Information With State and Foreign Government Officials

FDA is committed to cooperation with counterpart officials in State and foreign governments. Because public health problems respect neither State boundaries nor international borders, such cooperation is essential to consumer protection.

If FDA can provide foreign government officials with information on impending new or changed regulations and other requirements or activities, the agency can encourage adoption of uniform science-based measures that fully protect consumers, and can help reduce both duplication of regulatory activities and unfounded or contradictory regulatory requirements. FDA likewise benefits from the ability to receive drafts of proposed regulations from foreign and State government officials without being required to disclose these drafts to an FOIA requester because the risk of such public disclosure frequently inhibits foreign and State counterparts from full disclosure of useful information to FDA. For continuity in regulatory harmonization efforts at all levels of geopolitical organization (State, national, and international), FDA must be able to more freely communicate on regulatory matters and initiatives with counterpart government officials.

The following are examples of situations in which the ability to exchange nonpublic predecisional documents with State and foreign government counterparts would improve Federal-State uniformity and facilitate global harmonization of regulatory requirements.

1. Information exchange between FDA and its foreign government counterparts is necessary in order to utilize the technical expertise of other regulatory agencies for purposes of harmonizing regulations and regulatory activities. Current increases in worldwide trade, as well as recent trade agreements, add impetus to harmonization activities already underway. For example, FDA wanted to, but could not, disclose to

foreign counterpart officials at 1993 international meetings, the drafts of its proposed rules on medical device good manufacturing practices (published in the Federal Register of November 23, 1993 (58 FR 61952)), and on regulations of seafood safety through Hazard Analysis Critical Control Points (HACCP) (published in the Federal Register of January 28, 1994 (59 FR 4142)). FDA believes its harmonization and rulemaking activities in these areas would be enhanced by nonpublic exchange of such draft proposals.

2. The Food Code, published in the Federal Register of January 28, 1994 (59 FR 4085), consists of model requirements to safeguard public health and assure that food is unadulterated and honestly presented when offered to consumers. The Food Code was offered as a model for local, State, and Federal governmental jurisdictions to adopt under their own authorities as regulations for food service, retail food stores, or food-vending operations. Because concerns about confidentiality limited FDA's ability to exchange predecisional documents, access to developmental materials and drafts was limited to State government officials who were commissioned by FDA. Consequently, it was difficult for FDA to get technical contributions and professional views from the reservoir of expertise among many other State officials. FDA believes this limitation on nonpublic exchange is detrimental to Federal-State cooperation. By its very nature, the Food Code is central to public health programs of Federal, State, and local government organizations. As such, FDA would have preferred to share developmental materials and drafts with a spectrum of State government officials to assure participation in the development of the document by some of the officials who will rely on it in the course of their ongoing work.

3. The successful development and implementation of a comprehensive food safety strategy, beyond the program for seafood safety, will depend on a joint effort between FDA and State government officials. FDA's decisions would benefit greatly from exchange of technical expertise and professional views at all stages in the development of a strategy. The importance of State government input and partnership is underscored by the fact that, while FDA regulatory authority is very broad, in practice many phases of food production and distribution are regulated principally by State or local governments.

4. Some aspects of the Nutrition Labeling and Education Act (the NLEA)

address consumer issues that traditionally have been addressed by State governments in food label review, e.g., content descriptors, net weight declarations, and other elements that could relate to economic deception. Congress intended, and FDA desires, that there be a partnership between FDA officials and their State government counterparts in the education and enforcement aspects of this legislation. However, although FDA has been able to involve State government officials who hold FDA commissions in strategy discussions, the agency has not been able to utilize the broader base of expertise that resides throughout State governments. Further, although the NLEA empowers the States to take action under the authority of the act, and requires the States to notify FDA prior to initiating any action, it requires the sharing of only very basic information. Enhanced ability to exchange nonpublic information between FDA and State government officials will facilitate enforcement of the NLEA.

5. The Mammography Quality Standards Act of 1992 (the MQSA), which is now being implemented, poses many challenges with regard to Federal-State cooperation and coordination. The MQSA calls for FDA to delegate the MQSA authority to States that meet certain requirements, and for FDA to provide oversight to ensure that States fulfill their responsibilities. One objective of the MQSA is to maintain a certain consistency of standards across State programs. Like the Federal government, States establishing new programs and standards are bound by administrative rulemaking processes, and will want to undertake those rulemakings as soon as possible. So long as FDA's regulations limit the nonpublic exchange of draft regulations, States may draft rules that will turn out to be inconsistent with FDA's. That inconsistency may delay and frustrate implementation of the provisions of the MQSA that are intended to encourage State involvement in programs to assure quality mammography. If FDA and State officials could exchange draft regulations at all stages of the process, States could propose regulations that were consistent with Federal regulations within coordinated timeframes.

The enforcement and sanctions processes for the MQSA also pose challenges to Federal-State cooperation and coordination. There are approximately 11,300 facilities to be inspected, only about 30 percent of which will be inspected by FDA. Strategies for inspection priorities and Federal-State uniformity in the

application of enforcement actions and sanctions will be very important. If FDA cannot easily exchange nonpublic information with State government officials, cooperative efforts may be less effective.

F. Summary of Background

Exchanges of nonpublic information that meet the conditions established in the proposal will facilitate Federal-State uniformity and international harmonization in order to maximize consumer protection and minimize the possibility that unnecessarily disparate measures will be adopted on a particular issue. In order to enhance effective regulatory activities and expeditious review of significant public health issues, FDA has concluded that it needs the ability, in selected circumstances, to disclose confidential commercial information to State government officials, just as it earlier determined that it may be necessary at times to disclose such information to foreign government officials. Furthermore, in order to prepare new regulations or modify existing regulations, issue technical requirements, or undertake a variety of other activities, FDA may need to exchange draft proposals with counterpart State government or foreign government officials in the same way it exchanges similar information with other U.S. government agencies. Federal-State uniformity and international harmonization are facilitated when such exchanges can take place at early stages under circumstances that allow the frank exchange of views among technical experts. FDA's experience over the last decade has convinced the agency that foreign and State government technical and scientific staff perform the same advisory function, in many instances, as other agency employees and that the recommendations of such experts are important to effective decisionmaking.

Of course, any information provided by State or foreign government officials upon which FDA is relying in proposing a new regulation or proposed change in existing regulations would be included in published proposals or final rules in accordance with the Administrative Procedure Act (5 U.S.C. 553). The general public will have ample opportunity to comment on such proposals and their bases at that time. FDA also emphasizes that disclosures to foreign and State counterparts under final regulations based on these proposals would not be a routine occurrence, but would occur only in limited situations.

II. Proposed Amendments

A. The Proposal to Extend to State Government Officials the Recent Regulatory Provisions for Exchanging Confidential Commercial Information With Foreign Government Officials

Proposed § 20.88(d) covers the nonpublic disclosure of certain information that is protected from mandatory public disclosure by exemption 4 of the FOIA, 5 U.S.C. 552(b)(4) to State government officials. Exemption 4 covers two broad categories of information in Federal agency records: Trade secret information, and information that is: (1) Commercial or financial, (2) obtained from a person, and (3) privileged or confidential ("confidential commercial information").

Trade secret information has been defined by the courts as information relating to the making, preparing, compounding, or processing of trade commodities (*Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983)). This definition, which requires a "direct relationship" between the trade secret and the productive process, applies to a relatively narrow category of information that coincides with information prohibited from disclosure under section 301(j) of the act (21 U.S.C. 331(j)). FDA recently amended § 20.61 to reflect this definition (59 FR 531, January 5, 1994). That amendment was part of an update of the agency's FOIA regulations to reflect changes that were required by the 1986 amendments to the FOIA and which have already been put into practice by the agency. The amended definition of "trade secret" in part 20 is a restatement of the standard established by *Public Citizen Health Research Group*, and puts the definition in conformity with applicable case law and with HHS's FOIA regulations. Because FDA's practice has been in accordance with the judicial standards that resulted from *Public Citizen Health Research Group* and with the definitions established by HHS, the amendment to § 20.61 did not alter the agency's practice in any way or the expectations of the public or regulated industry concerning FDA's treatment of particular types of information.

Nor will the proposed amendment to § 20.88 alter FDA's existing practice with respect to the narrow category of information that can be considered "trade secret." The proposed amendment to § 20.88 expressly excludes the disclosure of information that would fall into the trade secret category to State government officials, without the express authorization of the

submitter. The only exception is that State scientists visiting FDA as part of a joint review or long-term training effort authorized under section 708 of the act (21 U.S.C. 379) may, under additional safeguards specified in the rule, be allowed access to such information.

It has been an agency practice to disclose confidential information, including trade secret information, to visiting government scientists insofar as that access is authorized under confidentiality agreements for a training or joint review activity under section 708 of the act and § 20.90. This proposed rule (§ 20.88(d)(1)(ii)(C)) codifies the procedures for providing access to such information in the rule on exchanging information with State government officials rather than continuing this practice under the more general § 20.90 procedures.

The principal focus of this part of the proposed rulemaking is the disclosure to State government officials of the other category of information covered by exemption 4 of the FOIA, "confidential commercial information," including agency-prepared reviews of such information, and records that include such information. Commercial or financial information that a person is required to provide FDA is "confidential" for purposes of exemption 4 if disclosure of the information is likely to: (1) Impair the Government's ability to obtain necessary information in the future or (2) cause substantial harm to the competitive position of the person from whom the information was obtained. (See *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 877-880 (D.C. Cir. 1992) (en banc), cert. denied, 113 S.Ct. 1579 (1993); *National Parks and Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).) Commercial or financial information that is provided to FDA on a voluntary basis is "confidential" if it is of a kind that the provider would not customarily release to the public. (See *Critical Mass Energy Project* at 880). The types of information that may be exempt from public disclosure pursuant to this section of the FOIA include: Business sales statistics, customer and supplier lists, research data, profit and loss data, and overhead and operating costs. Under many circumstances, FDA also treats data supporting product approval submissions as confidential commercial information that is entitled to be prohibited from public disclosure. Thus, under the amended regulation, confidential commercial information submitted to the agency that could be disclosed to State governments would

include information (other than trade secret information prohibited from disclosure under section 301(j) of the act) in pending and approved submissions for permission to perform studies on or to market regulated articles such as new drugs, new animal drugs, medical devices, and biological products, and information in agency-prepared reviews of such submissions.

The proposed amendment to § 20.88 would establish that State government officials are not members of the public for purposes of disclosure of confidential commercial information submitted to FDA or incorporated into records prepared by the agency, and that such disclosures would not invoke the requirements in § 20.21 of uniform access to records. Disclosure of confidential commercial information to State government officials pursuant to the proposed amendment would be an "authorized" disclosure. Accordingly, no FDA employee engaged in such a nonpublic disclosure of confidential commercial information would be in violation of the Trade Secrets Act, 18 U.S.C. 1905. That statute makes the unauthorized disclosure of such information by a Federal employee a crime.

The proposed amendment to § 20.88 will enable FDA, in its discretion and subject to the conditions imposed by this proposed amendment, to provide or receive confidential commercial information (whether provided by the sponsor or found in investigatory records) in nonpublic exchanges with State government officials for use in cooperative regulatory efforts or law enforcement efforts. FDA will be able to make such exchanges of confidential commercial information contained in submissions, in FDA- or State government-prepared reviews and records of such submissions, and in FDA- or State government-prepared investigatory records, without invoking the rule established in § 20.21 that any member of the public becomes entitled to the same information.

The agency does not intend that disclosures of confidential commercial information to State government officials will be a routine occurrence. FDA intends to engage in the disclosure of nonpublic confidential commercial information to State government officials only when certain conditions are met, and only in its discretion. In every case, the proposed rule (§ 20.88(d)(1)(i)) would require assurances from the State government that the information will be held in confidence. The proposed rule (§ 20.88(d)(1)(ii)) would further require that any one of three additional

conditions be met: (1) Written authorization by the submitter of the information; (2) a finding that disclosure is in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of the product or information concerning an investigation, or by reason of the State government being able to exercise its regulatory authority more expeditiously than the agency; or (3) the disclosure is to a State government scientist visiting FDA as part of a joint review or long-term cooperative training effort that furthers FDA's regulatory mission. Thus, the circumstances and safeguards under which FDA would exchange confidential commercial information with State government officials pursuant to the proposed amendment to § 20.88 would be the same as those recently provided in the 1993 amendment to § 20.89 regarding FDA disclosure of confidential commercial information to foreign government officials.

B. Proposals for Regulatory Provisions for Exchanging Predecisional Documents and Other Nonpublic Information With State and Foreign Government Officials

The agency is proposing to amend §§ 20.88(e) and 20.89(d) to cover the nonpublic exchange between FDA and State government officials (§ 20.88(e)) and between FDA and foreign government officials (§ 20.89(d)), of nonpublic predecisional documents concerning FDA's and other governments' proposed regulations, impending regulatory initiatives, or other nonpublic information relevant to agency activities (including, but not limited to, draft regulations, guidelines for technical issues to be addressed in sponsors' submissions, draft staff manual guides, draft compliance policy guides, strategy documents for inspection priorities, and draft MOU's between State, Federal, and foreign government agencies).

FDA wants the ability, in some circumstances and only when specific conditions are met, to exchange predecisional, preimplementation, or other nonpublic documents with State government officials and foreign government officials, without being compelled to disclose them to the public.

For the purposes of § 20.88(e) of this proposed regulation, the term "official of a State government agency" may include an official of an organization of State officials having responsibility to facilitate harmonization of State standards and requirements in FDA's areas of responsibility. Similarly, for the

purposes of § 20.89(d) of this proposed regulation, the term "foreign government official" may include an official of an international organization having responsibility to facilitate harmonization of global standards and requirements in FDA's areas of responsibility. Examples of organizations whose officials may be given access to draft nonpublic documents are the Association of Food and Drug Officials (AFDO) and the Food and Agriculture Organization (FAO) of the United Nations.

The ability to exchange predecisional and preimplementation documents with the officials in question will facilitate harmonization of national and international regulatory requirements.

In every case, the proposed regulations (§§ 20.88(e)(1)(i) and 20.89(d)(1)(i)) require assurances from the receiving government that the information will be held in confidence. The proposed regulations (§§ 20.88(e)(1)(ii) and 20.89(d)(1)(ii)) further require the agency to determine that it is reasonably necessary to exchange the nonpublic documents to enhance Federal-State uniformity or to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of obligations resulting from international agreements. When these conditions are met, the agency believes that the records will be exempt from mandatory public disclosure under the FOIA.

C. FDA Believes the Deliberative Process Privilege Should Protect Certain Advice and Recommendations from Foreign and State Counterparts

The proposed amendments (§§ 20.88(e)(2) and 20.89(d)(2)) would establish that State and foreign government officials are not members of the public for purposes of exchange of certain nonpublic predecisional records, and that such exchanges will not invoke the requirements in § 20.21 of uniform access to records. FDA believes that records of advice and recommendations between government officials concerning public health and harmonization initiatives can be protected from mandatory disclosure under exemption 5 of the FOIA, 5 U.S.C. 552(b)(5). That exemption incorporates common law discovery privileges for intra- and interagency memoranda, including the deliberative process privilege asserted by government agencies to protect the process and quality of decisionmaking.

FDA believes it is appropriate to assert the deliberative process privilege 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.

In order to encourage the most candid and useful exchange of information in these circumstances, FDA believes it is essential to have discretion to protect from public disclosure the advice and recommendations it receives from State or foreign government officials. Again, the same policy considerations apply as would apply to intraagency deliberations: State and foreign government officials are at least as likely as Federal employees to be inhibited from giving frank advice when they know that opinion will be made public.

The principle that documents generated outside a government "agency" may still qualify for protection from public disclosure under exemption 5 of the FOIA has been endorsed by many courts. In recognizing the practical necessity that requires agency decisionmaking to depend on advice and opinions from sources beyond agency or Federal personnel, courts have adopted a "functional" test for assessing the applicability of exemption 5 protection, and included a variety of "nonagencies" within the threshold definition of exemption 5 memoranda. (See, e.g., *Formaldehyde Institute v. HHS*, 889 F.2d 1118, 1123-1124 (D.C. Cir. 1989) (exemption 5's interagency threshold requirement applied to opinions solicited from outside scientific journal reviewers); *Ryan v. Department of Justice*, 617 F.2d 781, 790

(D.C. Cir. 1980) (exemption 5 applied to recommendations from Senators to Attorney General); *Mobil Oil Corp. v. FTC*, 406 F. Supp. 305, 315 (S.D.N.Y. 1976) (exemption 5 rationale applies to advice from State as well as Federal agencies). FDA believes the examples it has described in this document demonstrate that it is appropriate and necessary for FDA to be able to treat the exchange of advice and recommendations from foreign and State government officials as a functional part of the agency's deliberative process.

In addition to protecting certain advice and recommendations from State and foreign government officials which FDA utilizes in its decisionmaking processes, FDA also believes it should be able to cooperate with State and foreign government officials who request FDA input for deliberations within their own agencies.

Those State and foreign government agencies with which FDA most frequently consults operate, as does FDA, within laws that constrain their ability to share nonpublic information. In many circumstances, these agencies require assurances that FDA will not disclose to the public in response to a FOIA request certain information provided to FDA by a State or foreign government official. FDA has always been able to give such assurances with respect to proprietary or law enforcement information provided by State or foreign governments; under FDA's public information regulations, such information is subject to the same protection as if the information had been directly gathered or received by FDA. (See § 20.88(c)(1) and 20.89(a)). Indeed, FDA's regulations have for 20 years permitted the agency to provide additional assurances with respect to investigatory records that the State or foreign government will provide only upon assurance that protection will continue for some longer period of time. *Id.*

However, FDA has not been able to provide similar assurances of confidentiality with respect to nonpublic information provided to FDA by State or foreign governments that is of a deliberative nature, reflecting internal deliberations of that other government entity or predecisional drafts of records that are intended to implement public health initiatives on the part of counterpart State or foreign government agencies.

As discussed above, FDA believes that when such counterpart officials provide advice to FDA on issues and initiatives that FDA is deliberating, that advice is the functional equivalent of advice that

would be provided by experts within the agency or by other Federal agency employees. Accordingly, under the amendments proposed to §§ 20.88 and 20.89, FDA would protect as interagency memoranda under exemption 5 of the FOIA the records it exchanged with foreign and State government health officials as part of FDA's efforts to reach a decision about initiatives it was considering. However, FDA believes the public health and FDA's relationships with foreign and State counterparts require that the agency be able to provide similar consultations to counterpart officials when it is those State or foreign government officials who request advice, and who require the exchange to remain nonpublic in order to protect their own deliberative processes. In most cases, because the foreign or State counterpart is providing FDA with information that is confidential commercial or investigatory information, FDA's published regulations permit FDA to protect those records from public disclosure. There have been situations, however, where a foreign government agency wishes to share with FDA a document that will not qualify for protection under the FOIA for proprietary or investigatory records, and which may not qualify under the deliberative process privilege discussed above because the decision that is being made is entirely within the jurisdiction of the foreign government counterpart. FDA believes international comity and the potential benefit to public health that may result from such consultations require the agency to attempt to honor such requests for confidentiality whenever it is possible to do so.

In circumstances where advice or information is provided by foreign governments pursuant to international agreements that provide for the nondisclosure of such exchanges, FDA believes the record generated by the foreign government and provided to FDA is not necessarily an "agency record" subject to FOIA and that FDA, therefore, might honor requests for confidentiality without contravening public disclosure requirements. The Supreme Court has delineated two broad tests for determining whether a document is an agency record for purposes of FOIA. The document: (1) Must be created or obtained by an agency, and (2) must be under the control of the agency when a FOIA request for the record is made. See *United States Department of Justice v. Tax Analysts*, 492 U.S. 136 (1989). When a foreign government shares

documents pursuant to agreements that require confidentiality before disclosure will be made, the record may not be under the "control" of FDA. In those circumstances where a treaty, agreement, or MOU between the United States and a foreign government requires confidentiality in order to encourage international consultation, FDA believes that control of the record may be governed by the treaty or agreement under which the foreign government health officials have shared the information with United States counterparts. Two recent opinions by Federal District Courts in the District of Columbia support this view. See *Katz v. National Archives & Records Administration*, No. 92-1024 (D.D.C. March 2, 1994), *reconsideration denied* (D.D.C. August 24, 1994) (appeal pending) (autopsy records not agency records because their disposition was governed by a Deed of Gift to National Archives); *KDKA-TV v. Richard Thornburgh, et. al*, No. 90-1536 (D.D.C. September 30, 1992) (reports in possession of National Transportation Safety Board not agency record because disclosure is governed by conditions of International Convention).

Similarly, FDA believes that in those rare instances where State governments initiate review of their own proceedings through consultation with FDA on conditions of confidentiality, FDA should be able to offer advice without jeopardizing public disclosure of records that would interfere with the deliberative processes of the State agency. FDA invites the submission of further information and views on this issue.

D. FDA's Proposals Will Not Reduce Public Access to Agency Records

FDA believes these proposals will do nothing to diminish current public access to agency records. The purpose of these proposed amendments is not to reduce the number or types of records that will be available to the public from FDA, but to enhance the agency's access to information exchanges that it currently is not able to undertake.

FDA fully supports the Attorney General's Memorandum of October 4, 1993, establishing new standards of government openness, and FDA intends to apply a "foreseeable harm" standard when applying FOIA exemptions. Under this policy, government agencies are guided by the principle that exempt information should not be withheld from a FOIA requester unless it need be. FDA reiterates that the nonpublic exchange of information with State and foreign government counterparts will not be a routine occurrence; the

proposed regulations, which require specific assurances from the receiving official and a determination on the part of FDA that the exchange is necessary, establish rigorous prerequisites.

FDA has no intention of protecting from public disclosure any information it shares with foreign or State counterparts that may be disclosed to the public without harm to any private or government interests. Nor does FDA believe that all State or foreign counterparts will desire or require FDA to protect information they provide to this agency. However, the agency also believes that its current public information regulations are too rigid for effective exchange of information in a national and increasingly international economy. These proposals reflect FDA's determination that its public health mission has been hampered in certain circumstances by the inability to exchange nonpublic information with counterpart officials. The agency believes the proposed changes have been drafted narrowly and with sufficient safeguards to allow FDA to exchange nonpublic information when necessary without damage to either proprietary interests or appropriate public access to agency records.

As stated earlier, 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.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed 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 proposed rule is consistent with the regulatory

philosophy and principles identified in the Executive Order. In addition, the proposed 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 this proposed rule promotes harmonized regulatory requirements, nationally and internationally, thereby reducing disparate regulatory requirements, the agency certifies that the proposed 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.

V. Comments

Interested persons may, on or before April 27, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation of 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.

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 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 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 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.

Dated: January 23, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

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