

**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