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