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, 242a, 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