

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