alter that balance. Another comment claimed that an executive branch agency cannot withhold information from the public, stating that only Congress could authorize such action.

The agency disagrees with the comments. The preamble to the proposed rule considered this issue and explained why the agency believes that the proposed rule is consistent with the FOIA. FOIA (5 U.S.C. 552) is a disclosure statute and its exemptions are intended to be discretionary. As stated earlier, those exemptions establish several categories of information that can be withheld from public disclosure. The categories relevant to FDA include: (a) Trade secret and confidential commercial information to protect intellectual property rights and research incentives (5 U.S.C. 552(b)(4)); (b) predecisional documents to protect the deliberative process (5 U.S.C. 552(b)(5)); (c) information whose disclosure might invade personal privacy (5 U.S.C. 552(b)(6)); and (d) investigatory files compiled for law enforcement purposes to protect investigations (5 U.S.C. 552(b)(7)).

For disclosures of confidential commercial information under § 20.88(d), the preamble to the proposed rule explained that the FOIA protects two broad categories of information from mandatory public disclosure: Trade secret information and ''information that is: (1) Commercial or financial, (2) obtained from a person, and (3) privileged or confidential ('confidential commercial information').'' (See 60 FR 5530 at 5535.) The preamble to the proposed rule explained that the proposed rule did not alter agency practice with respect to protecting trade secret information (except to permit disclosure to visiting State scientists) and that disclosures of confidential commercial information to State government officials in accordance with the conditions of the proposed rule would not be a public disclosure and would be ''authorized'' under the Trade Secrets Act. (See 60 FR 5530 at 5536.)

The preamble to the proposed rule also explained why the provisions regarding predecisional documents and other nonpublic information are consistent with the FOIA. The preamble characterized exchanges of nonpublic, predecisional documents between FDA and State and foreign governments as being of the same character as interagency memoranda and letters that are exempt from disclosure under the FOIA. The preamble to the proposed rule stated that:

> * * * it is appropriate to assert the deliberative process privilege [to disclosure under the FOIA] 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.

(See 60 FR 5530 at 5536 and 5537.) The preamble to the proposed rule noted that courts have applied a ''functional'' test for assessing the applicability of the exemption for intra- and interagency memoranda and letters and have included ''nonagencies'' within the exemption. Id.

The preamble also noted that in circumstances where advice or information is provided by foreign governments pursuant to international agreements that require confidentiality as a condition of exchange, FDA believes that a record so provided is not necessarily an ''agency record'' subject to FOIA. Id. at 60 FR 5537 through 5538. The agency cited recent court decisions suggesting that FDA could honor requests for confidentiality under these circumstances without contravening public disclosure requirements established by Congress. Id.

Thus, the final rule is consistent with the FOIA, and the agency declines to amend the final rule to require public access to documents beyond that required by the FOIA.

6. One comment said that FDA should discuss the proposed rule's potential effects, costs, and implications in a public forum.

FDA believes that notice and comment rulemaking has provided a satisfactory public forum for this issue.

7. Three comments said that FDA cannot ensure that no unauthorized disclosures of confidential commercial information will occur and cannot take effective action against State or foreign government officials if unauthorized disclosures occur. Two comments added that the agency should describe how it intends to monitor and investigate reports of unauthorized disclosures and take action against those employees making unauthorized disclosures. One comment suggested that FDA establish a mechanism to track such unauthorized disclosures, analyze and report any patterns or trends in unauthorized disclosures, and, if FDA becomes aware of any unauthorized disclosures by State or foreign government officials, notify the company whose confidential commercial information was disclosed and cease information exchanges with the State or foreign government.

FDA cannot guarantee that no unauthorized disclosures of confidential commercial information will ever occur, but it does note that procedures already exist for investigating reports of unauthorized disclosures. In 1994, the agency created the Office of Internal Affairs (OIA). OIA consists of one Special Agent in Charge and a team of Special Agents. These agents are trained criminal investigators and report directly to the Commissioner of Food and Drugs or the Deputy Commissioner/ Senior Advisor. FDA described OIA's functions in a notice published in the Federal Register of January 23, 1995 (60 FR 4417 and 4418). In brief, OIA:

- Provides a centralized Agencywide investigative resource for the Commissioner, the Deputy Commissioners, and top Agency management;
- Provides a centralized investigative liaison between FDA and the Office of the Inspector General (OIG);
- Serves as an FDA investigative resource to conduct internal FDA investigations and to support OIG investigations; and

OIA is also responsible for investigating all allegations of misconduct by FDA employees. (See 59 FR 67087, December 28, 1994.) To assist in this task, the office uses a data base to track cases by type of investigation. One investigation type is ''Unauthorized Release of Information.''

Whenever OIA receives any report of unauthorized disclosures of information, OIA investigates the report and works with the OIG where appropriate. If the investigation suggests that Federal laws were violated, this information is presented to the OIG and may be referred to the Department of Justice for prosecution. These same resources and procedures could be applied, in cooperation with State and