include information (other than trade secret information prohibited from disclosure under section 301(j) of the act) in pending and approved submissions for permission to perform studies on or to market regulated articles such as new drugs, new animal drugs, medical devices, and biological products, and information in agency-prepared reviews of such submissions.

The proposed amendment to § 20.88 would establish that State government officials are not members of the public for purposes of disclosure of confidential commercial information submitted to FDA or incorporated into records prepared by the agency, and that such disclosures would not invoke the requirements in § 20.21 of uniform access to records. Disclosure of confidential commercial information to State government officials pursuant to the proposed amendment would be an "authorized" disclosure. Accordingly, no FDA employee engaged in such a nonpublic disclosure of confidential commercial information would be in violation of the Trade Secrets Act. 18 U.S.C. 1905. That statute makes the unauthorized disclosure of such information by a Federal employee a

The proposed amendment to § 20.88 will enable FDA, in its discretion and subject to the conditions imposed by this proposed amendment, to provide or receive confidential commercial information (whether provided by the sponsor or found in investigatory records) in nonpublic exchanges with State government officials for use in cooperative regulatory efforts or law enforcement efforts. FDA will be able to make such exchanges of confidential commercial information contained in submissions, in FDA- or State government-prepared reviews and records of such submissions, and in FDA- or State government-prepared investigatory records, without invoking the rule established in § 20.21 that any member of the public becomes entitled to the same information.

The agency does not intend that disclosures of confidential commercial information to State government officials will be a routine occurrence. FDA intends to engage in the disclosure of nonpublic confidential commercial information to State government officials only when certain conditions are met, and only in its discretion. In every case, the proposed rule (§ 20.88(d)(1)(i)) would require assurances from the State government that the information will be held in confidence. The proposed rule (§ 20.88(d)(1)(ii)) would further require that any one of three additional

conditions be met: (1) Written authorization by the submitter of the information; (2) a finding that disclosure is in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of the product or information concerning an investigation, or by reason of the State government being able to exercise its regulatory authority more expeditiously than the agency; or (3) the disclosure is to a State government scientist visiting FDA as part of a joint review or longterm cooperative training effort that furthers FDA's regulatory mission. Thus, the circumstances and safeguards under which FDA would exchange confidential commercial information with State government officials pursuant to the proposed amendment to § 20.88 would be the same as those recently provided in the 1993 amendment to § 20.89 regarding FDA disclosure of confidential commercial information to foreign government officials.

B. Proposals for Regulatory Provisions for Exchanging Predecisional Documents and Other Nonpublic Information With State and Foreign Government Officials

The agency is proposing to amend §§ 20.88(e) and 20.89(d) to cover the nonpublic exchange between FDA and State government officials (§ 20.88(e)) and between FDA and foreign government officials (§ 20.89(d)), of nonpublic predecisional documents concerning FDA's and other governments' proposed regulations, impending regulatory initiatives, or other nonpublic information relevant to agency activities (including, but not limited to, draft regulations, guidelines for technical issues to be addressed in sponsors' submissions, draft staff manual guides, draft compliance policy guides, strategy documents for inspection priorities, and draft MOU's between State, Federal, and foreign government agencies).

FDA wants the ability, in some circumstances and only when specific conditions are met, to exchange predecisional, preimplementation, or other nonpublic documents with State government officials and foreign government officials, without being compelled to disclose them to the public.

For the purposes of § 20.88(e) of this proposed regulation, the term "official of a State government agency" may include an official of an organization of State officials having responsibility to facilitate harmonization of State standards and requirements in FDA's areas of responsibility. Similarly, for the

purposes of § 20.89(d) of this proposed regulation, the term "foreign government official" may include an official of an international organization having responsibility to facilitate harmonization of global standards and requirements in FDA's areas of responsibility. Examples of organizations whose officials may be given access to draft nonpublic documents are the Association of Food and Drug Officials (AFDO) and the Food and Agriculture Organization (FAO) of the United Nations.

The ability to exchange predecisional and preimplementation documents with the officials in question will facilitate harmonization of national and international regulatory requirements.

In every case, the proposed regulations (§§ 20.88(e)(1)(i) and 20.89(d)(1)(i)) require assurances from the receiving government that the information will be held in confidence. The proposed regulations (§§ 20.88(e)(1)(ii) and 20.89(d)(1)(ii)) further require the agency to determine that it is reasonably necessary to exchange the nonpublic documents to enhance Federal-State uniformity or to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of obligations resulting from international agreements. When these conditions are met, the agency believes that the records will be exempt from mandatory public disclosure under the FOIA.

C. FDA Believes the Deliberative Process Privilege Should Protect Certain Advice and Recommendations from Foreign and State Counterparts

The proposed amendments (§§ 20.88(e)(2) and 20.89(d)(2)) would establish that State and foreign government officials are not members of the public for purposes of exchange of certain nonpublic predecisional records, and that such exchanges will not invoke the requirements in $\S\bar{2}0.21$ of uniform access to records. FDA believes that records of advice and recommendations between government officials concerning public health and harmonization initiatives can be protected from mandatory disclosure under exemption 5 of the FOIA, 5 U.S.C. 552(b)(5). That exemption incorporates common law discovery privileges for intra- and interagency memoranda, including the deliberative process privilege asserted by government agencies to protect the process and quality of decisionmaking.

FDA believes it is appropriate to assert the deliberative process privilege in response to requests for public access