Amendment because citizens had not yielded to the Federal government their ''rights of access to the information generated by our public servants.''

The agency disagrees with the comment. The final rule concerns FDA's ability to exchange certain confidential commercial information or nonpublic, predecisional documents with State or foreign government officials. Thus, the final rule pertains to information exchange and access to FDA records and implements Federal authority without impairing State or popular power. Indeed, the final rule can strengthen States' regulatory roles.

3. Two comments said that the proposed rule violated procedural due process because it would give State and foreign government officials ''preferential access'' to predecisional documents, such as draft regulations, thereby giving those officials ''far greater influence over the deliberative process by imparting selected information and opinion'' to FDA.

The agency disagrees with the comments' assertion. As the Supreme Court said in *Mathews* v. *Eldridge*, 424 U.S. 319, 332 (1976), procedural due process ''imposes constraints on governmental decisions which deprive individuals of 'liberty' or property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.'' However, ''[d]ue process, unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances * * * [d]ue process is flexible and calls for such procedural protections as the particular situation demands.'' Id. p. 334 (citations omitted).

Here, the final rule does not impose any constraints or sanctions nor does it deprive individuals of any liberty or property interest. The final rule does not ''deprive'' the public of its access to confidential commercial information or predecisional documents because such information has always been protected from disclosure. Neither does the final rule deprive the public of the opportunity to comment on rulemaking. As stated in the preamble to the proposed rule:

> * * * 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.

(See 60 FR 5530 at 5538.) This approach is consistent with due process because ''[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner,''' *Mathews*, 424 U.S. 333 (citations omitted).

Moreover, judicial opinions concerning informal rulemaking have focused on the need to ensure that ex parte contacts do not frustrate judicial review or raise serious questions of fairness. (See *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9 (D.C. Cir. 1977), *cert. denied* 434 U.S. 829, *rehearing denied* 434 U.S. 988 (1977).) There is no *per se* prohibition on ex parte contacts. (See *Action for Children's Television* v. *FCC*, 564 F.2d 458, 475 n.28 (D.C. Cir. 1977).)

FDA reiterates that it will include in its published proposals any information provided by State or foreign government officials upon which FDA is relying. The agency will make such information available at the time of publication. Thus, 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. FDA believes this is consistent with all applicable legal requirements.

4. Two comments claimed that the proposed rule violated rights of privacy and confidentiality because information supplied to FDA, with the expectation that the information would remain confidential, would be eligible for disclosure to officials outside FDA. The comments noted that non-FDA officials may have interests and obligations that differ from those of FDA, the public, or the regulated industry. The comments said that requiring the State or foreign government to provide a written statement establishing its authority to protect confidential commercial information or nonpublic documents from public disclosure was ''wholly inadequate'' because State and foreign officials are not subject to FDA's management or control. The comments further asserted that much information given to FDA is unreliable, fraudulent, or defamatory and could be used by outside parties for ulterior purposes and that the proposed rule would dissuade submission of confidential information to FDA and encourage submission of false information.

Four other comments expressed similar objections to the proposed rule, stating that foreign governments might use confidential commercial information to benefit their own industries.

The agency has given serious attention to the concerns expressed in the comments, but disagrees that the safeguards are inadequate. As stated earlier, FDA issued a final rule on November 19, 1993, to permit the agency to disclose confidential commercial information to foreign government officials, subject to certain conditions and safeguards to protect the confidentiality of the information. Since issuing that final rule, the agency is unaware of any misuse or unauthorized disclosure of confidential commercial information supplied to a foreign government. In almost all cases, disclosure occurred with the knowledge and consent of the company that submitted the confidential commercial information to FDA. Thus, FDA's experience with the 1993 final rule indicates that confidential commercial information provided to a foreign government official remains confidential and is not used to benefit the foreign government's industry.

Furthermore, FDA emphasizes that the decision to share information with a foreign government is discretionary and that the agency will deny a foreign government's request for confidential commercial information if the foreign government officials are unable to assure FDA of their ability to protect the information. FDA will also deny access where there is a lack of scientific data or regulatory expertise to contribute to a product review or laboratory or clinical investigation, unless the foreign government intends to use the information for law enforcement purposes. (See 58 FR 61598 at 61600.) Similar standards will apply to exchanges with State governments and State government officials.

FDA also disagrees with the assertion that parties often submit false information to the agency. Submitting false information to the government is a Federal crime under 18 U.S.C. 1001. Submission of false or misleading reports with respect to medical devices is prohibited under section 301(q)(2) of the act (21 U.S.C. 331(q)(2)). Submission of false information may also lead to debarment under section 306 of the act (21 U.S.C. 335a) or assessment of civil money penalties under section 303(g) or 307 of the act (21 U.S.C. 333(g) or 335b). FDA has taken legal action against parties that have submitted false information to the agency and emphasizes that it will not tolerate the submission of false information to the agency.

5. Two comments asserted that the proposed rule was contrary to congressional intent, as expressed in the FOIA, to provide information to the public. The comments explained that the FOIA's exceptions to disclosure represented a balance between the public's ''right to know'' and the government's interest in not disclosing certain types of information. Thus, the comments claimed, only Congress can