available to the public. Sections 20.88(e) and 20.89(d) pertain to exchanges of nonpublic, predecisional documents with State and foreign government officials. Historically, FDA has generally withheld these documents from public disclosure as well.

The agency also disagrees with any assertion that the final rule violates the First Amendment. While courts have construed the First Amendment as giving the public access to government proceedings, they have declined to provide access to all government operations. Indeed, as the Supreme Court stated in *Press-Enterprise Co.* v. *Superior Court of California*, 478 U.S. 1, 9 (1986):

Although many governmental processes operate best under public scrutiny, it takes little imagination to recognize that there are some kinds of government operations that would be totally frustrated if conducted openly.

In the present case, requiring FDA to publicly disclose confidential commercial information and predecisional documents that it provides to or receives from State and foreign governments would frustrate the final rule's fundamental purposes. The final rule is intended to encourage information exchanges between governments by assuring State and foreign governments that the information or documents they receive or provide will not be publicly available. The final rule also reassures those who submit confidential commercial information to FDA or to State or foreign governments that such information will be protected. If public access to confidential commercial information were required whenever FDA exchanged such information with a State or foreign government, as the comments suggest, firms would then be obliged to refuse requests for intergovernmental disclosure by FDA, State governments, or foreign governments or even refuse to submit confidential commercial information in order to protect it.

Additionally, courts have established a two-part test of "experience" and "logic" to determine whether the First Amendment requires the governmental proceeding to be open to the public. The first part, "experience," asks whether the proceeding is one that has historically been open to the public. The second part, "logic," asks whether public access would play a significant, positive role in the governmental process. If the government process passes these tests, then a qualified First Amendment right of public access exists; in other words, the right of public access is not absolute or

unconditional. (See *Press-Enterprise Co.*, 478 U.S. 8 and 9; *United States* v. *Simone*, 14 F.3d 833, 837–839 (3d Cir. 1994).)

Applying the two-part test to the final rule leads to the conclusion that the First Amendment does not require these exchanges of information to be open to the public. Historically, the agency has always protected confidential commercial information and indicated that predecisional documents prepared by the agency are either not available to the general public or available under limited conditions. (See, e.g., 21 CFR 20.61 and 21 CFR 20.62 (nondisclosure of inter- or intra-agency memoranda or letters); 21 CFR 20.64 (nondisclosure of records or information compiled for law enforcement purposes); 21 ČFR 10.80 (establishing conditions for release of draft notices and regulations).

Additionally, under the second prong, it is questionable whether public access would play a significant, positive role in the governmental process. For example, intergovernmental exchanges of confidential commercial information will enable governments to learn more about specific products and, as a result, to develop better and more efficient regulatory or enforcement actions. At the same time, disclosure of such confidential commercial information to the general public does not further any regulatory process, and in any event, is prohibited by 18 U.S.C. 1905. The law recognizes that public disclosure of confidential commercial information may have a detrimental effect on product development; providing a firm's competitors with access to valuable information may create a disincentive for firms to develop innovations or improve their products or methods. The result would be diminished availability of useful products.

Furthermore, intergovernmental exchanges of nonpublic, predecisional documents may help the agency decide whether a regulatory approach it is considering is appropriate or even necessary. While the agency may, in many cases, make draft documents available to the general public (for example, in the Federal Register of July 24, 1995 (60 FR 37856), FDA published a notice announcing the availability of a draft final rule on medical device good manufacturing practices to members of the public as well as to State and foreign regulators), in other cases, providing public access to predecisional documents during the deliberative process could interfere with that process or create misleading impressions about the agency's intentions.

In some cases, premature public disclosure of draft documents can

unnecessarily complicate regulatory actions and undermine public health and safety. For example, if the agency developed a proposal on a particular form of tamper evident packaging, such information could be helpful to other foreign governments. However, premature disclosure of that same information could ultimately prove harmful to the general public if its disclosure would enable those who tamper with products to alter their methods in order to evade detection or to defeat the proposed solution.

FDA further emphasizes that, as stated in the preamble to the proposed rule, if any State or foreign government official provides information that the agency wishes to rely on in its published proposals or the administrative record, the agency will include that information unless inclusion would harm private or governmental interests (see 60 FR 5530 at 5538). When a proposed rule is published, therefore, the general public would be fully informed and have an opportunity to comment on the substance of any advice from State or foreign officials that FDA incorporated into the proposed rule.

The agency reiterates that nonpublic exchanges of information with State and foreign government officials will not be a routine occurrence and that FDA does not intend to prohibit public disclosure of information received from State and foreign government officials if such information can be disclosed without harm to any private or governmental interests.

More importantly, the agency believes that the final rule will result in significant public benefits because the final rule facilitates FDA's access to information and expertise within State and foreign governments and should result in better regulatory proposals and actions. For example, if FDA and a State are considering whether to issue proposed regulations on the same or similar subjects, exchanging nonpublic, predecisional documents might lead both parties to reexamine, modify, or harmonize their proposed regulatory strategy. Preventing the issuance of redundant or unnecessary regulations should benefit the public and the affected industries.

2. One comment claimed that the proposed rule violated the Tenth Amendment to the Constitution. The Tenth Amendment states that, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." The comment argued that the proposed rule violated the Tenth