quality of a product or information concerning an investigation; or (3) the disclosure is to a State government scientist visiting FDA on the agency's premises as part of a joint review or cooperative training effort, and FDA (a) retains physical control over the information, (b) requires a written commitment to protect the confidentiality of the information, and (c) implements specific conflicts-of-interest safeguards.

E. Cooperation and Harmonization Needs for Exchanging Nonpublic Predecisional Documents and Other Nonpublic Information With State and Foreign Government Officials

FDA is committed to cooperation with counterpart officials in State and foreign governments. Because public health problems respect neither State boundaries nor international borders, such cooperation is essential to consumer protection.

If FDA can provide foreign government officials with information on impending new or changed regulations and other requirements or activities, the agency can encourage adoption of uniform science-based measures that fully protect consumers, and can help reduce both duplication of regulatory activities and unfounded or contradictory regulatory requirements. FDA likewise benefits from the ability to receive drafts of proposed regulations from foreign and State government officials without being required to disclose these drafts to an FOIA requester because the risk of such public disclosure frequently inhibits foreign and State counterparts from full disclosure of useful information to FDA. For continuity in regulatory harmonization efforts at all levels of geopolitical organization (State, national, and international), FDA must be able to more freely communicate on regulatory matters and initiatives with counterpart government officials.

The following are examples of situations in which the ability to exchange nonpublic predecisional documents with State and foreign government counterparts would improve Federal-State uniformity and facilitate global harmonization of regulatory requirements.

1. Information exchange between FDA and its foreign government counterparts is necessary in order to utilize the technical expertise of other regulatory agencies for purposes of harmonizing regulations and regulatory activities. Current increases in worldwide trade, as well as recent trade agreements, add impetus to harmonization activities already underway. For example, FDA wanted to, but could not, disclose to

foreign counterpart officials at 1993 international meetings, the drafts of its proposed rules on medical device good manufacturing practices (published in the Federal Register of November 23, 1993 (58 FR 61952)), and on regulations of seafood safety through Hazard Analysis Critical Control Points (HACCP) (published in the Federal Register of January 28, 1994 (59 FR 4142)). FDA believes its harmonization and rulemaking activities in these areas would be enhanced by nonpublic exchange of such draft proposals.

2. The Food Code, published in the Federal Register of January 28, 1994 (59 FR 4085), consists of model requirements to safeguard public health and assure that food is unadulterated and honestly presented when offered to consumers. The Food Code was offered as a model for local, State, and Federal governmental jurisdictions to adopt under their own authorities as regulations for food service, retail food stores, or food-vending operations. Because concerns about confidentiality limited FDA's ability to exchange predecisional documents, access to developmental materials and drafts was limited to State government officials who were commissioned by FDA Consequently, it was difficult for FDA to get technical contributions and professional views from the reservoir of expertise among many other State officials. FDA believes this limitation on nonpublic exchange is detrimental to Federal-State cooperation. By its very nature, the Food Code is central to public health programs of Federal, State, and local government organizations. As such, FDA would have preferred to share developmental materials and drafts with a spectrum of State government officials to assure participation in the development of the document by some of the officials who will rely on it in the course of their ongoing work.

3. The successful development and implementation of a comprehensive food safety strategy, beyond the program for seafood safety, will depend on a joint effort between FDA and State government officials. FDA's decisions would benefit greatly from exchange of technical expertise and professional views at all stages in the development of a strategy. The importance of State government input and partnership is underscored by the fact that, while FDA regulatory authority is very broad, in practice many phases of food production and distribution are regulated principally by State or local governments.

4. Some aspects of the Nutrition Labeling and Education Act (the NLEA)

address consumer issues that traditionally have been addressed by State governments in food label review, e.g., content descriptors, net weight declarations, and other elements that could relate to economic deception. Congress intended, and FDA desires, that there be a partnership between FDA officials and their State government counterparts in the education and enforcement aspects of this legislation. However, although FDA has been able to involve State government officials who hold FDA commissions in strategy discussions, the agency has not been able to utilize the broader base of expertise that resides throughout State governments. Further, although the NLEA empowers the States to take action under the authority of the act, and requires the States to notify FDA prior to initiating any action, it requires the sharing of only very basic information. Enhanced ability to exchange nonpublic information between FDA and State government officials will facilitate enforcement of the NLEA.

5. The Mammography Quality Standards Act of 1992 (the MQSA), which is now being implemented, poses many challenges with regard to Federal-State cooperation and coordination. The MQSA calls for FDA to delegate the MQSA authority to States that meet certain requirements, and for FDA to provide oversight to ensure that States fulfill their responsibilities. One objective of the MQSA is to maintain a certain consistency of standards across State programs. Like the Federal government, States establishing new programs and standards are bound by administrative rulemaking processes, and will want to undertake those rulemakings as soon as possible. So long as FDA's regulations limit the nonpublic exchange of draft regulations, States may draft rules that will turn out to be inconsistent with FDA's. That inconsistency may delay and frustrate implementation of the provisions of the MQSA that are intended to encourage State involvement in programs to assure quality mammography. If FDA and State officials could exchange draft regulations at all stages of the process, States could propose regulations that were consistent with Federal regulations within coordinated timeframes.

The enforcement and sanctions processes for the MQSA also pose challenges to Federal-State cooperation and coordination. There are approximately 11,300 facilities to be inspected, only about 30 percent of which will be inspected by FDA. Strategies for inspection priorities and Federal-State uniformity in the