Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of FDA Safety Alert/Public Health Advisory

Section 705(b) (21 U.S.C. 375(b)) of the Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of recent alerts include spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) (42 U.S.C. 300u(a)(4)) of the Public Health Service Act authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly the problem discussed in the alert or advisory is identified, how easily the problem is understood, how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17	157

There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time was estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey, in addition to discussions with contacts in trade associations.

Dated: December 11,1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32189 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–96–4000]

Memorandum of Understanding Between the Food and Drug Administration and the United States Customs Service

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the FDA and the United States Customs Service. The purpose of this MOU is to establish a partnership between both agencies to participate in an international trade Compliance Measurement (CM) Program.

DATES: The agreement became effective October 23, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas D. Gardine, Division of Import Operations and Policy, Office of Regulatory Affairs (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and other shall be published in the Federal Register, the agency is publishing notice of an MOU.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

Memorandum of Understanding Between the United States Customs Service and the United States Food and Drug Administration

The parties of this Memorandum of Understanding (MOU) are the United States Food and Drug Administration, hereinafter called Customs.

The purpose of this MOU is to establish a partnership between both agencies to participate in an international trade Compliance Measurement (CM) Program.

The Customs CM Program assesses the potential risk that importations do not comply with the law based on a statistically valid random methodology. Customs has the authority to examine and detain all imported merchandise for the purpose of ensuring that such merchandise complies with all U.S. laws governing admissibility; or, Customs may conditionally release the merchandise under bond pending a final admissibility determination. This authority applies to merchandise for which a particular determination relating to admissibility is vested in other government agencies. To streamline initiatives in the area of public health and safety, Customs intends to work more closely with other Government agencies regarding commodities which pose a risk to the United States from a public health and safety standpoint. By working jointly with FDA to determine the compliance rates of specific commodities entering the United States, each agency intends to gain a better understanding of the public health and safety threat these commodities pose to the public. Coordinating activities as part of the CM Program is intended to enhance each agency's overall mission performance.

Specifically, this MOU provides the framework for the cooperative efforts of Customs and FDA under the Compliance Measurement Program to ensure maximum compliance with the laws enforced by both agencies and the regulations promulgated thereunder, and that appropriate procedures pertaining to importation are followed. This MOU is intended to establish improved communications between the signatories. Further, the goals of the MOU include increasing efficiency, reducing individual agency costs through the pooling of resources, and expediting clearance of compliant imported products into the United States. Having both agencies working together on the Customs CM Program assists in the implementation of the aforementioned goals.

This MOU serves to solidify our positions regarding cooperation among government agencies as described in Vice President Al Gore's Reports of the National Performance Review, From Red Tape to Results: Creating a Government That Works Better & Costs Less (1993) and the Government Performance and Results Act of 1993, 103 Pub. L. No. 62, 107 Stat. 285.

Both Customs and the FDA recognize that this MOU in no way compromises the efforts of both agencies in protecting the public health and safety of the United States from merchandise that falls outside the parameters of the Customs CM Program.

I. Customs Agrees To:

1. Incorporate into Customs FY 96 CM Program for the second quarter of the fiscal year (FY), the Harmonized Tariff Schedule (HTS) numbers FDA and Customs jointly agree to include in the program. These HTS numbers may be modified in the second quarter of FY 96 and beyond.

2. Notify FDA of all compliance measurement examination results of these selected products.

3. In accordance with FDA's written instructions, examine the products FDA and Customs jointly agree to be included in the CM Program.

4. Assign a representative to facilitate communication and interaction between Customs and FDA.

II. FDA Agrees To:

1. Provide Customs with written instructions to use to examine the products FDA and Customs jointly agree to be included in the CM Program.

2. Provide Customs with a list of HTS numbers and advise Customs of any changes to the list.

3. Provide training and/or material necessary to accomplish examination procedures, e.g., equipment, tools, forms, etc., as outlined in the examination instructions written by FDA.

4. Assign a representative to facilitate communication and interaction between Customs and FDA.

III. It is Mutually Understood And Agreed That:

1. This MOU is to develop a partnership between the two agencies with respect to Customs CM Program solely. This MOU does not supersede, or relate in any way, to any other MOU's signed by the two agencies. This MOU is to define in general terms the basis on which the parties concerned will cooperate and, as such, does not constitute a financial obligation to serve as a basis for expenditures. No transfer of Federal funds will be involved under this MOU.

2. This MOU is a FY 96–97 planning document. Implementation of the CM Program initiatives commence October 1, 1995.

3. The above provisions will be exercised to the extent authorized by law, Customs and FDA directives, statutes, and regulations, and will be consistent with the respective agency's missions. To that extent, it is understood that a Customs compliance measurement determines only whether there is reason to believe merchandise is noncompliant. Furthermore, Customs release of merchandise following a compliance measurement examination does not constitute a determination by Customs that the merchandise does or does not comply with FDA law. Any final determination of admissibility under FDA law remains vested in the FDA.

4. If, for any reason, the HTS numbers, examination instructions, or necessary training/materials, are not acceptable to either Customs or FDA, modifications will be made to ensure mutual agreement by both agencies.

5. This MOU is an internal Government agreement and is not intended to confer any right or benefit on any private person or party.

6. Information gathered as a result of the CM Program may be highly sensitive, proprietary information. Any information obtained by one agency from the other will be used only for the purpose of enforcing applicable laws and regulations; the information will not be released to third parties except as provided by statute or regulation. In accordance with 44 U.S.C. 3510, any information obtained by one agency from the other will continue to be subject to all the provisions of law of the originating agency.

7. Access to the information described in this MOU is based on the compliance of both FDA and Customs with the Privacy Act of 1974 (5 U.S.C. 552a).

8. This MOU shall become effective upon the date of final signature by both agencies and remain in effect for 5 years or until cancelled by either party upon a 30-day notice in writing.

This MOU may be amended or continued by mutual consent of the parties hereto in writing.

By: George J. Weise.

Title: Commissioner, United States Customs Service.

Date: October 23, 1995.

By: Mary K. Pendergast,

Title: Deputy Commissioner/Senior Advisor to the Commissioner, United States Food and Drug Administration, for the Commissioner of Food and Drugs.

[FR Doc. 96–32274 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–96–4006]

Memorandum of Cooperation Between the Food and Drug Administration and the Economy, Development, and Reconstruction Ministry of Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of cooperation (MOC) between FDA and the Economy, Development, and Reconstruction Ministry of Chile. The purpose of the MOC is to facilitate the trade of safe and wholesome fish and fishery products.

DATES: The agreement became effective May 13, 1996.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Office of Seafood (HFS–400), Food and Drug Administration, 1110 Vermont Ave. NW., Washington, DC 20005, 202–418–3150.