DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0022]

Agency Information Collection Activities Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 6, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(a)(2) and (e) (OMB Control No. 0910–0131—Reinstatement)

Under sections 501(c) and 502(a) of the act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(a)(2) and (e) (21 CFR 801.150(a)(2) and (e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(a)(2) and (e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship nonsterile products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. To discontinue this reporting and recordkeeping procedure would place an economic hardship on the industry and an additional burden on FDA to monitor products in interstate commerce for failure to comply with adulteration and misbranding provisions of the act.

The respondents to this collection of information are device manufacturers and contract sterilizers.

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

TABLE—1. ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150	90	20	1,800	4	7,200

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

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

Dated: August 27, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23507 Filed 9–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Memorandum of Understanding Between the Food and Drug Administration and the Department of Agriculture, Food and Forestry of Ireland

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 FDA and the Department of Agriculture, Food and Forestry of Ireland. The purpose of the MOU is to establish certification requirements for caseins, caseinates, and mixtures thereof.

DATES: The agreement became effective November 5, 1996.

FOR FURTHER INFORMATION CONTACT: Merton Smith, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

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

Dated: August 28, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

Memorandum of Understanding Between the Food and Drug Administration Department of Health and Human Services of the United States of America and the Department of Agriculture, Food and Forestry of Ireland Covering Caseins, Caseinates, and Mixtures Thereof Exported to the United States

I. Purpose

The Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America and the Department of Agriculture, Food and Forestry (DAFF) of Ireland upon signing this Memorandum of Understanding (MOU) intend to:

1. Establish certification requirements for the caseins, caseinates, and mixtures thereof exported from Ireland to the United States to assure that contaminated caseins, caseinates, and mixtures thereof will not be imported into the United States.
2. Minimize the need for extensive FDA audit sampling of these certified products from Ireland.

II. Definitions

For the purposes of this MOU, both participants concur in the following definitions:

LOT: A lot is a quantity of casein, caseinates, or mixtures thereof packaged by one manufacturer during a definite period of time not exceeding one (1) day. The manufacturing process, including milling and packaging, is performed by using a perfectly identified processing line. Caseins, caseinates, or mixtures thereof intended for export to the United States are packaged, after milling, in identical containers identified by a unique code or mark traceable to the manufacturer.

SALMONELLA-NEGATIVE: The absence of *Salmonella* in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from the same lot of product and tested using the procedures contained in the current edition of the *Bacteriological Analytical Manual* (see Section V. Analytical Methodology).

PHOSPHATASE-NEGATIVE: The absence of phosphatase activity in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from the same lot of product and tested using the method contained in the current edition of the *Official Methods of Analysis* (see Section V. Analytical Methodology).

III. Substance of MOU

A. The Department of Agriculture, Food and Forestry of Ireland

The Department of Agriculture, Food and Forestry of Ireland (DAFF) is the agency of the Irish government responsible for inspecting those caseins, caseinates, and mixtures thereof that are intended for export. Such inspection is necessary for consumer protection. To fulfill its responsibilities under this Memorandum of Understanding, DAFF intends to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption in that they comply with the requirements of the Food, Drug, and Cosmetic Act of the United States, of the Public Health Service Act of the United States, and of this Memorandum of Understanding. DAFF intends to inspect and analyze samples of these caseins, caseinates, and mixtures thereof to ensure that they comply with these requirements.

To discharge its responsibilities regarding caseins, caseinates, and mixtures thereof and to fulfill its commitment under this MOU, DAFF plans to:

1. Inspect and analyze each lot of caseins, caseinates, and mixtures thereof produced in Ireland for export to the United States to assure that it is *Salmonella*-negative and phosphatase-negative, based on the testing of thirty (30) subsamples of twenty-five (25) gram units taken from bags in a lot of caseins, caseinates, and mixtures thereof immediately before closing, as determined by the methods cited in Section V. Analytical Methodology.
2. Require that all containers of a lot of caseins, caseinates, and mixtures thereof that are to be exported to the United States be certified as comply with the provisions of this Memorandum of Understanding, and identified by a lot number, and all other information required by the Federal Food, Drug, and Cosmetic Act of the United States.
3. Require that all of the information that is required by the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act of the United States be included on the label and labeling of individual products.
4. Furnish FDA with a copy of the current Irish regulations and the procedures used to ensure that the caseins, caseinates, and mixtures thereof are in compliance with those regulations and with the Food, Drug, and Cosmetic Act and the Public Health Service Act of the United States.
5. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure that the caseins, caseinates, and mixtures thereof that are produced are fit for human consumption, as discussed in III. A. Substance of MOU.

B. The Food and Drug Administration of the United States of America

FDA is charged with the enforcement of the Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes of the United States. FDA directs its activities toward the protection of the public health in the United States by ensuring that foods are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure compliance with these statutes. FDA makes a concerted effort to ensure that foods entering the United States meet the same standards as domestic products. To discharge these responsibilities regarding caseins, caseinates, and mixtures thereof and to fulfill this Memorandum of Understanding, FDA plans to:

1. Audit samples of caseins, caseinates, and mixtures thereof certified by DAFF under this Memorandum of Understanding to ensure that the products exported from Ireland and offered for import into the United States comply with the requirements of the Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes of the United States.
2. Share any information obtained through its audit sampling with DAFF and the First Secretary of the Embassy of Ireland.
3. Promptly notify DAFF and the First Secretary of the Embassy of Ireland of the detention of any caseins, caseinates, and mixtures thereof covered by this Memorandum of Understanding.
4. Share expertise and provide consultative assistance to DAFF when necessary to assure the safety of the caseins, caseinates, and mixtures thereof exported to the United States.

IV. Sample Collection

The same samples should be used to determine both the presence, if any, of *Salmonella* and the level of phosphatase activity.

Each sample will consist of thirty (30) subsamples of caseins, caseinates, or mixtures thereof. Each subsample will consist of approximately twenty-five (25) grams that will be collected in accordance with the applicable portions of the current edition of the *Bacteriological Analytical Manual* (see Section V. Analytical Methodology).

V. Analytical Methodology

Compliance with the established criteria for *Salmonella* and phosphatase should be determined according to the methods contained in the current editions of *Bacteriological Analytical Manual* for *Salmonella* and *Official Methods of Analysis* for phosphatase.

These publications are available from:
AOAC International
481 North Frederick Avenue, Suite 500
Gaithersburg, MD 20877
Telephone number: 301–924–7077
Telefax number: 301–924–7089

VI. Participating Parties

A. The Department of Agriculture, Food and Forestry, Agriculture House, Kildare Street, Dublin 2, Ireland

B. Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, USA

VII. Liaison Officers

A. For the Department of Agriculture, Food and Forestry: Principal Officer, Milk Policy Division, (Currently, Mr. Tom Moran), Department of Agriculture, Food and Forestry, Agriculture House, Kildare Street, Dublin 2, Ireland

For the Embassy of Ireland: First Secretary, (Currently, Ms. Kate Slattery), 2234 Massachusetts Avenue, N.W., Washington,

DC 20008. Telephone number: 202–452–3939

B. For the Food and Drug Administration: Director, International Activities Staff, (Currently, Mr. Charles W. Cooper), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C Street, S.W., Washington, DC 20204. Telephone number: 202–205–5042, Telefax number: 202– 205–0165

VIII. Administrative Procedures

The participants mutually consent on the ways and means of giving instructions and guidance for the practical implementation and application of this Memorandum of Understanding.

The obligations under this MOU are intended to be non-binding.

IX. Period of MOU

Activities under this Memorandum of Understanding commence upon signature by both participants for a period of five (5) years and may, at the conclusion of that period, with the consent of both participants, be extended for an additional five (5) years. The participants plan to evaluate the MOU sometime during each five (5) year period. The MOU may be extended or revised by mutual consent, or terminated by either participant, upon a thirty (30) day advance written notice to the other.

For the Department of Agriculture, Food and Forestry of Ireland
By: K. Slattery
Title: First Secretary, Embassy of Ireland
Date: November 5, 1996
Place: Rockville, Maryland

For the Food and Drug Administration, Department of Health and Human Services of the United States of America
By: M. A. Friedman
Title: Deputy Commissioner for Operations, U.S. Food and Drug Administration
Date: November 5, 1996
Place: Rockville, Maryland

[FR Doc. 97–23451 Filed 9–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A35, Rockville, MD 20857, (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated her responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on April 10, 1997, through June 24, 1997.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Bureau of Health Professions, 5600 Fishers Lane, Room 8–05, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Laurie Duplease on behalf of Alexis Duplease, New Haven, Connecticut, Court of Federal Claims Number 97–0270 V
2. James Gimesky on behalf of Jenna Lynn Gimesky, Ann Arbor, Michigan, Court of Federal Claims Number 97–0280 V
3. Shari M. and John G. Lawlor on behalf of Brooke D. Lawlor, Omaha, Nebraska, Court of Federal Claims Number 97–0285 V