Deratting Certificates. The U.S. Public Health Service (PHS), specifically CDC, is delegated the responsibility for providing these services, as provided in 42 CFR Section 71.46.

Until a major restructuring in the 1970's greatly reduced the number of ports at which PHS assigned staff, these services were regularly performed by PHS staff at 18 large ports and more than 100 smaller ports, as manpower permitted. Since 1977, almost all inspections have been performed under contract by qualified pest control operators at these same ports, at no cost to the owners or agents of the ships inspected. In contrast, most nations pass along the costs associated with these services to those who benefit from them.

Deratting Exemption Certificates Not Required Since 1985

Because of worldwide derat certification activities and modern rat-proofing of ships, CDC determined in 1985 that no adverse impact on the public health would result from not requiring vessels from foreign ports to have a valid Deratting Exemption Certificate. As a result, the United States has not required Deratting Exemption Certificates for the last twelve years. This change resulted in a more economical rodent inspection program without any adverse consequences or increased risk to the public health.

Consolidation of Inspections and Deratting Certificate Issuance

CDC has now determined that consolidation of the number of ports at which inspections are conducted and Deratting Certificatess are issued will further economize the program without jeopardizing the public health.

Accordingly, beginning October 1, 1997, CDC started conducting rodent infestation inspections at eleven specified ports. Six of these ports were selected because of the proximity of PHS staff who can conduct inspections as necessary and ensure quality control. The five additional ports add geographic dispersion and provide additional opportunities for those seeking inspection services.

Article 20 of the International Health Regulations requires that notice be given to WHO when the list of ports designated in application of the International Health Regulations is changed. This notification has been made.

Applicability

The list of ports at which rodent infestation inspections are conducted and Deratting and Deratting Exemption Certificates are issued represents the only ports designated for this purpose. CDC staff or contract representatives are not available to conduct inspections at any other port.

Dated: April 3, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9334 Filed 4–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89N–0474]

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 May 11, 1998.

ADDRESSES: Submit written comments on the collection of information to 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: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Geriatric Use Labeling for Human Prescription Drugs—21 CFR 201.57(f)(10)

In a final rule published on August 27, 1997 (62 FR 45313), FDA amended its regulations governing the content and format of labeling for human prescription drug products, including biological products, to include information on the appropriate use of drugs for persons age 65 years and older. The regulations facilitate access to this information by establishing a new ''Geriatric Use'' subsection in the labeling. The purpose of the regulation that will become effective on August 27, 1998, is to promote safe and effective use of prescription drugs among older people.

The regulations were issued under FDA's authority to regulate the labeling of prescription drugs and biological products, including sections 502(a), (f), and (j), and 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a), (f), and (j), and 355) and section 351 of the Public Health Service Act (42 U.S.C. 242).

In the final rule (62 FR 45313 at 45324), FDA requested comments on the information collection provisions of the new regulations. No comments were received in response to this request.

Respondents to this collection of information will be business, and other for-profit organizations, including small business and manufacturers.FDA estimated the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)	290	1	290	120	34,800

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

Dated: April 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9349 Filed 4–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0149]

Guidance for Industry on National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs.'' This guidance is intended to clarify the administrative processes that will be followed in implementing the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Copies of this guidance for industry may be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the guidance entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs.'' Section 412 of Title IV of FDAMA, signed into law by President Clinton on November 21, 1997, amended section 502(e)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(e)(1)) to add as a requirement that the established name and quantity or, if determined to be appropriate, the proportion of each active ingredient appear on the label of all over-the-counter (OTC) drug products intended for human use. FDAMA amended section 502(e)(1) of the act to require the listing of inactive ingredients on drug product labels, including the labels of OTC drug products intended for human use.

In addition, in the **Federal Register** of February 27, 1997 (62 FR 9024), FDA issued a proposed rule that would establish a standardized format for the labeling of OTC drug products. The rule, which is being finalized, is intended to make labeling for OTC drug products easier to read and understand. This guidance for industry advises manufacturers, packers, and distributors of the agency's current thinking on implementing these provisions of FDAMA, as they apply to OTC drug products, in coordination with the forthcoming finalization of the proposed OTC labeling rule.

This guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday

Dated: March 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–9350 Filed 4–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2246–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Approval as an Accrediting Organization: the Joint Commission on Accreditation of Healthcare Organizations, the American Association of Blood Banks, and the American Osteopathic Association

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continued approval of accrediting organizations for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program for the following organizations: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Association of Blood Banks (AABB), and the American Osteopathic Association (AOA). This represents a continuation of the initial exemptions published in the **Federal Register** on—

- January 3, 1995 (60 FR 130)—JCAHO.
- July 21, 1995 (60 FR 37660)—AABB.
- July 21, 1995 (60 FR 37657)—AOA.

We have found that the accreditation process of these organizations provides reasonable assurance that the laboratories accredited by them meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by one or more of these organizations (as applicable) and continue to meet the organization's requirements would meet the CLIA condition level requirements for laboratories. Therefore, laboratories accredited by one or more of these organizations (as applicable) are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective on April 9, 1998 through June 30, 1999 for the JCAHO, and July 21, 2001 for the AABB and the AOA.

FOR FURTHER INFORMATION CONTACT:
Joan Simmons, (410) 786–3408 (JCAHO)
Virginia Wanamaker, (410) 786–3384 (AABB)
Kathleen Todd, (410) 786–3385 (AOA)