Services of Public Health. In the Spring of 2001, CDC conducted field tests with the local public health governance instruments in the State of Massachusetts.

CDC received approval to implement a voluntary data collection to assess the capacity of local boards of health to deliver the Essential Public Health Services. This data collection will provide a framework for local boards of health to evaluate their effectiveness. Electronic data submission will be the method of choice. If computer technology in local jurisdictions does not support electronic submission, hard copy survey instruments will be available. Local jurisdictions using hard copy survey instruments will receive assistance from State or local level field coordinators for web-based data entry.

Local boards of health will respond to the survey. An estimated 33% of approximately 3,200 United States local boards are expected to participate in the National Performance Standards Program per year. The burden hours are estimated to be 19,200.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)
Local Boards of Health Year 1	1,066	1	6
Local Boards of Health Year 2	1,067	1	6
Local Boards of Health Year 3	1,067	1	6

Dated: Friday, October 14, 2003.

Gaylon D. Morris,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 03–26987 Filed 10–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0278]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 2003 (68 FR 58974 at 59067), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0520. The approval expires on October 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

October 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27189 Filed 10–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0486]

Determination That PIPRACIL (Piperacillin Sodium) 2-Gram, 3-Gram, and 4-Gram Vials Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillin sodium 2-gram, 3-gram, and 4-gram vials.

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

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of

safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials are the subject of approved NDA 50–545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals). PIPRACIL is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. The holder of the application for PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials has informed FDA that the drug products have been withdrawn from sale.

The agency has determined that Wyeth-Ayerst's PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports and has found no information that would indicate these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Wyeth-Ayerst's PIPRACIL 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials may be approved by the agency.

Dated: October 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27190 Filed 10–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: September 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of September 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

OFFICE OF INVESTIGATION, OFFICE OF INSPECTOR GENERAL—DHHS CASE INVESTIGATION MANAGEMENT SYSTEM

[For press release from 09/01/2003–09/30/2003]

Subject name	Address	Effective date
Program-Related Convictions		
Arca, William	Oceanside, NY	10/20/2003
Arias, Grisel	Miami, FL	10/20/2003
Arias, Idania	Miami, FL	10/20/2003
Badalyan, Arsen	Van Nuys, CA	10/20/2003
Batiste, Vernida	Marrero, LA	10/20/2003
Benson, Kelly	North Mankato, MN	10/20/2003
Bishop, Michael	Casa Grande, AZ	10/20/2003
Boisseau, Carlene	Chester, VA	10/20/2003
Boland, C	Easley, SC	10/20/2003
Bouza, Vicente	Miami, FL	10/20/2003
Burgos, Marco	Miami Beach, FL	10/20/2003
Burgos, Suzanne	Miami Beach, FL	10/20/2003
Carter, Valarie	Los Angeles, CA	10/20/2003
Cash, Lenard	San Antonio, TX	10/20/2003
Clark, Merle	Oceanside, NY	10/20/2003
Clements, Deborah	Whitehall, OH	10/20/2003
Coppin, Leslie	Highlands Ranch, CO	10/20/2003
Cortez, Josie	Alhambra, CA	10/20/2003
Crow, Ronald	Beaver, WV	10/20/2003
Curran, Joan	Avon, OH	10/20/2003
De Jesus, Lorna	Long Beach, CA	10/20/2003
Deshields, Cynthia	Philadelphia, PA	10/20/2003
Dewan, Suman	New Orleans, LA	12/4/2002
Donaghy, Thomas	Whitehall, OH	10/20/2003
Donohue, Joseph	Sheridan, OR	10/20/2003
Edgar, Daniel	Peachtree City, GA	10/20/2003
EMA Medical Laboratory, Inc	Ridgewood, NY	10/20/2003
Exsted, Melody	Sandstone, MN	10/20/2003
Feldman, Gary	Lompoc, CA	10/20/2003
Ferran, Osmin	Miami, FL	10/20/2003
Flemons, Michael	Venus, TX	10/20/2003
Franklin, Dwonne	Minneapolis, MN	10/20/2003
Gezvkarayan, Khachik	Eloy, AZ	10/20/2003