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