information, FDA believes that maintenance of these records is a usual and customary part of normal business practices for these firms. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The third requirement is that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping requirement is provided in table 1 of this document. The estimate is based on the time required to develop written procedures.

Respondents to this collection of information are individuals or firms that manufacture, blend, process distribute, or use feed or feed ingredients that contain or may contain protein that may be derived from mammalian tissue.

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

TABLE1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
589.2000(e)(1)(iv)	1,030	1	1,030	14	14,420

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

The estimated number of respondents, persons that separate mammalian and nonmammalian materials, is derived from inspections of firms handling animal protein intended for use in animal feed. The estimate of the time required for this recordkeeping requirement is based on agency records and communication with industry.

Dated: February 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4023 Filed 2–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2607]

Agency Information Collection Activities; Announcement of OMB Approval; Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 22, 1999 (64 FR 63817), 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 0910–0171. The approval expires on January 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4021 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Agency Information Collection Activities; Announcement of OMB Approval; Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of March 19, 1999 (64 FR 13591), 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 0910–0429. The approval expires on December 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4022 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 99D–0297]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.