most recent cases. The information will be used to better evaluate the need for control of helminth parasites in fish intended for raw consumption and to evaluate effective means for control where such controls are found necessary. A national representative sample of 1,000 clinical gastroenterologists will be selected by a random procedure and interviewed by questionnaire.

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

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
500	1	500	.50	250

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

This is a one time survey. The burden estimate is based on FDA's experience with conducting similar surveys.

Dated: February 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4020 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0505]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Protein Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements placed on handlers of ruminant protein to prevent the establishment and amplification of bovine spongiform encephalopathy in the United States by ensuring that ruminant animal feed does not contain animal protein derived from mammalian tissue.

DATES: Submit written comments on the collection of information by April 24, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506 (c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR Part 589 (OMB Control Number 0910–0339—Extension)

This rule (§ 589.2000 (21 CFR 589.2000)) provides that protein derived from mammalian tissue (with some exceptions) for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348). Proteins derived from animal tissues contained in such feed ingredients in distribution cannot be readily identified (i.e., species) by recipents engaged in the manufacture, processing, distribution, and use of animal feeds and feed ingredients.

Thus, under the agency's authority in section 701(a) of the act (21 U.S.C. 371(a)), to issue regulations for the efficient enforcement of the act, this rule places three general requirements on persons that manufacture, blend, process, distribute, or use products that contain or may contain protein derived from mammalian tissues and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by FDA. This labeling requirement is exempt from the scope of the PRA because it is a ''public disclosure of information originally supplied by the Federal Government for the purpose of disclosure to the public'' (5 CFR 1329.3(c)(2)).

The second requirement is for establishments to maintain and make available to FDA, records that are sufficient to track any material that contains protein derived from mammalian tissues (as defined in § 589.2000(a)(1)), throughout the material's receipt, processing, and distribution. Based on available

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]

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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.