

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Assessment	1,720	1	1.00	1,720
Teacher Survey/TCR	2,580	1	0.50	1,290
Principal Survey	1,462	1	0.33	487
Year 2 (fall 2007):				
Parent Tracking Interview	4,667	1	0.166	778
Year 2 (spring 2008):				
Parent Tracking Interview	2,108	1	0.166	351
Parent Interview	2,042	1	1.00	2,042
Child Assessment	2,042	1	1.00	2,042
Teacher Survey/TCR	3,063	1	0.50	1,532
Principal	1,736	1	0.33	579

Estimated Total Annual Burden Hours: 6,484

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@ach.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, E-mail address: Karen_T._Matsuoka@omb.eop.gov, Attn: Desk Officer for ACF.

Dated: November 28, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0472]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited from Use in Animal Food or Feed; Animal Proteins 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending OMB approval on the existing recordkeeping requirements for this information collection, regarding animal proteins prohibited in ruminant feed.

DATES: Submit written or electronic comments on the collection of information by February 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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, Jr., Office of the Chief Information Officer (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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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 589.2000(e)(1)(iv) (OMB Control Number 0910-0339)—Extension

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and

distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

The respondents for this collection of information are manufacturers and or distributors of products that contain or may contain protein derived from

mammalian tissues and feeds made from such products.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
589.2000 (e)(1)(iv)	400	1	400	14	5,600

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

Dated: November 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0475]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit written or electronic comments on the collection of information by February 2, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Human Tissue Intended for Transplantation—21 CFR Part 1270 (OMB Control Number 0910-0302)—Extension

Under section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Sections 1270.31(a) through (d) (21 CFR 1270.31(a) through (d)) require written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process; (2) all significant steps in obtaining, reviewing, and assessing the relevant medical records of the donor; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Sections 1270.31(a) and (b) also require recording and justification of any deviation from the written procedures. Section 1270.33(a) (21 CFR 1270.33(a)) requires records to be maintained concurrently with the performance of each significant step in the procedures of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and such records required under § 1270.21 (21 CFR 1270.21). Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35 (21 CFR 1270.35) requires specific