TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
2018 Second Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	[2] 0.5	1,600
2019 Third and Final Data Collection—Restaurant Segment (includes two facility types)	1,600	1	1,600	[2] 0.5	800
2020 Third and Final Data Collection—Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	[2] 0.5	1,200
2021 Third and Final Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	[2] 0.5	1,600
Total					10,900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Report of the FDA Retail Food Program Steering Committee, ''Database of Foodborne Illness Risk Factors (2000).'' Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2001/ucm123544.htm.*

2. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorstudies/ucm089696.htm.*

3. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/RetailFoodRiskFactorStudies/ucm224682.pdf.*

4. FDA National Retail Food Team, ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm223293.htm.*

5. ''FDA Food Code.'' Available at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm.*

Dated: October 23, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–26472 Filed 10–26–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by November 28, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0456. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

PHS Guideline on Infectious Disease Issues in Xenotransplantation—(OMB Control Number 0910–0456)—Extension

The statutory authority to collect this information is provided under sections 351 and 361 of the Public Health Service (PHS) Act (42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 301 *et seq.*). The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and to the general public. The PHS guideline is intended to address public health issues raised by xenotransplantation, through identification of general principles of prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to the public health. The collection of information described in this guideline is intended to provide general guidance on the following topics: (1) The development of xenotransplantation clinical protocols; (2) the preparation of submissions to FDA; and (3) the conduct of xenotransplantation clinical trials. Also, the collection of information will help ensure that the sponsor maintains important information in a cross-referenced system that links the relevant records of the xenotransplantation product recipient, xenotransplantation product, source animal(s), animal procurement center, and significant nosocomial exposures. The PHS

guideline describes an occupational health service program for the protection of health care workers involved in xenotransplantation procedures, caring for xenotransplantation product recipients, and performing associated laboratory testing. The PHS guideline is intended to protect the public health and to help ensure the safety of using xenotransplantation products in humans by preventing the introduction, transmission, and spread of infectious diseases associated with xenotransplantation.

The PHS guideline also recommends that certain specimens and records be maintained for 50 years beyond the date of the xenotransplantation. These include: (1) Records linking each xenotransplantation product recipient with relevant health records of the source animal, herd or colony, and the specific organ, tissue, or cell type included in or used in the manufacture of the product (3.2.7.1); (2) aliquots of serum samples from randomly selected animal and specific disease investigations (3.4.3.1); (3) source animal biological specimens designated for PHS use (3.7.1); animal health records (3.7.2), including necropsy results (3.6.4); and (4) recipients' biological specimens (4.1.2). The retention period is intended to assist health care practitioners and officials in surveillance and in tracking the source of an infection, disease, or illness that might emerge in the recipient, the source animal, or the animal herd or colony after a xenotransplantation.

The recommendation for maintaining records for 50 years is based on clinical experience with several human viruses that have presented problems in human to human transplantation and are therefore thought to share certain characteristics with viruses that may pose potential risks in xenotransplantation. These characteristics include long latency periods and the ability to establish persistent infections. Several also share the possibility of transmission among individuals through intimate contact with human body fluids. Human immunodeficiency virus (HIV) and Human T-lymphotropic virus are human retroviruses. Retroviruses contain ribonucleic acid that is reverse-transcribed into deoxyribonucleic acid (DNA) using an enzyme provided by the virus and the human cell machinery. That viral DNA can then be integrated into the human cellular DNA. Both viruses establish persistent infections and have long latency periods before the onset of disease, 10 years and 40 to 60 years, respectively. The human hepatitis viruses are not retroviruses, but several share with HIV the characteristic that they can be transmitted through body fluids, can establish persistent infections, and have long latency periods, e.g., approximately 30 years for Hepatitis C.

In addition, the PHS guideline recommends that a record system be developed that allows easy, accurate, and rapid linkage of information among the specimen archive, the recipient's medical records, and the records of the source animal for 50 years. The development of such a record system is a one-time burden. Such a system is intended to cross-reference and locate relevant records of recipients, products, source animals, animal procurement centers, and nosocomial exposures.

Respondents to this collection of information are the sponsors of clinical studies of investigational xenotransplantation products under investigational new drug applications (INDs) and xenotransplantation product procurement centers, referred to as source animal facilities. There are an estimated two respondents who are sponsors of INDs that include protocols for xenotransplantation in humans. Other respondents for this collection of information are an estimated four source animal facilities that provide source xenotransplantation product material to sponsors for use in human xenotransplantation procedures. These four source animal facilities keep medical records of the herds/colonies as well as the medical records of the individual source animal(s). The total annual reporting and recordkeeping burden is estimated to be approximately 45 hours. The burden estimates are based on FDA's records of xenotransplantation-related INDs and estimates of time required to complete the various reporting, recordkeeping, and third-party disclosure tasks described in the PHS guideline.

FDA is requesting an extension of OMB approval for the following reporting, recordkeeping, and third-party disclosure recommendations in the PHS guideline:

TABLE 1—REPORTING RECOMMENDATIONS

PHS Guideline section	Description
3.2.7.2	Notify sponsor or FDA of new archive site when the source animal facility or sponsor ceases operations.

TABLE 2—RECORDKEEPING RECOMMENDATIONS

PHS Guideline section	Description
3.2.7	Establish records linking each xenotransplantation product recipient with relevant records.
4.3	Sponsor to maintain cross-referenced system that links all relevant records (recipient, product, source animal, animal procurement center, and nosocomial exposures).
3.4.2	Document results of monitoring program used to detect introduction of infectious agents which may not be apparent clinically.
3.4.3.2	Document full necropsy investigations including evaluation for infectious etiologies.
3.5.1	Justify shortening a source animal's quarantine period of 3 weeks prior to xenotransplantation product procurement.
3.5.2	Document absence of infectious agent in xenotransplantation product if its presence elsewhere in source animal does not preclude using it.
3.5.4	Add summary of individual source animal record to permanent medical record of the xenotransplantation product recipient.
3.6.4	Document complete necropsy results on source animals (50-year record retention).
3.7	Link xenotransplantation product recipients to individual source animal records and archived biologic specimens.
4.2.3.2	Record baseline sera of xenotransplantation health care workers and specific nosocomial exposure.
4.2.3.3 and 4.3.2	Keep a log of health care workers' significant nosocomial exposure(s).
4.3.1	Document each xenotransplant procedure.

TABLE 2—RECORDKEEPING RECOMMENDATIONS—Continued

PHS Guideline section	Description
5.2	Document location and nature of archived PHS specimens in health care records of xenotransplantation product recipient and source animal.

TABLE 3—DISCLOSURE RECOMMENDATIONS

PHS Guideline section	Description
3.2.7.2	Notify sponsor or FDA of new archive site when the source animal facility or sponsor ceases operations.
3.4	Standard operating procedures (SOPs) of source animal facility should be available to review bodies.
3.5.1	Include increased infectious risk in informed consent if source animal quarantine period of 3 weeks is shortened.
3.5.4	Sponsor to make linked records described in section 3.2.7 available for review.
3.5.5	Source animal facility to notify sponsor when infectious agent is identified in source animal or herd after xenotransplantation product procurement.

In the **Federal Register** of June 14, 2012 (77 FR 35683), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from the public. The comment was not responsive to the comment request on the four specified aspects of the collection of information and did not provide any data or explanation that would support a change regarding the information collection requirements.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

PHS Guideline section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
3.2.7.2 [2]	1	1	1	0.50 (30 minutes)	0.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA is using one animal facility or sponsor for estimation purposes.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

PHS Guideline section	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
3.2.7 [2]	1	1	1	16	16
4.3 [3]	2	1	2	0.75 (45 minutes)	1.50
3.4.2 [4]	2	16	32	0.25 (15 minutes)	8
3.4.3.2 [5]	2	4	8	0.25 (15 minutes)	2
3.5.1 [6]	2	0.50	1	0.50 (30 minutes)	0.50
3.5.2 [6]	2	0.50	1	0.25 (15 minutes)	0.25
3.5.4	2	1	2	0.17 (10 minutes)	0.34
3.6.4 [7]	2	4	8	0.25 (15 minutes)	2
3.7 [7]	4	2	8.0	0.08 (5 minutes)	0.64
4.2.3.2 [8]	2	25	50	0.17 (10 minutes)	8.50
4.2.3.2 [6]	2	0.50	1	0.17 (10 minutes)	0.17
4.2.3.3 and 4.3.2 [6]	2	0.50	1	0.17 (10 minutes)	0.17
4.3.1	2	1	2	0.25 (15 minutes)	0.50
5.2 [9]	2	6	12	0.08 (5 minutes)	0.96
Total					41.53

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] A one-time burden for new respondents to set up a recordkeeping system linking all relevant records. FDA is using one new sponsor for estimation purposes.
[3] FDA estimates there is minimal recordkeeping burden associated with maintaining the record system.
[4] Monitoring for sentinel animals (subset representative of herd) plus all source animals. There are approximately 6 sentinel animals per herd × 1 herd per facility × 4 facilities = 24 sentinel animals. There are approximately 8 source animals per year (see footnote 7 of this table); 24 + 8 = 32 monitoring records to document.
[5] Necropsy for animal deaths of unknown cause estimated to be approximately 2 per herd per year × 1 herd per facility × 4 facilities = 8.
[6] Has not occurred in the past 3 years and is expected to continue to be a rare occurrence.
[7] On overage 2 source animals are used for preparing xenotransplantation product material for one recipient. The average number of source animals is 2 source animals per recipient × 4 recipients annually = 8 source animals per year. (See footnote 5 of table 3 of this document.)
[8] FDA estimate there re approximately 2 clinical centers doing xenotransplantation procedure × approximately 25 health care workers involved per center = 50 health care workers.
[9] Eight source animal records + 4 recipient records = 12 total records.

TABLE 6—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

PHS Guideline section	No. of respondents	No. of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
3.2.7.2 [2]	1	1	1	0.50 (30 minutes)	0.50
3.4 [3]	4	0.50	2	0.08 (5 minutes)	0.16
3.5.1 [4]	4	0.25	1	0.25 (15 minutes)	0.25
3.5.4 [5]	4	1	4	0.50 (30 minutes)	2
3.5.5 [4]	4	0.25	1	0.25 (15 minutes)	0.25
Total					3.16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA is using one animal facility or sponsor for estimation purposes.
[3] FDA's records indicate that an average of two INDs is expected to be submitted per year.
[4] To our knowledge, has not occurred in the past 3 years and is expected to continue to be a rare occurrence.
[5] Based on an estimate of 12 patients treated over a 3-year period, the average number of xenotransplantation produce recipients per year is estimated to be 4.

Because of the potential risk for cross-species transmission of pathogenic persistent virus, the guideline recommends that health records be retained for 50 years. Since these records are medical records, the retention of such records for up to 50 years is not information subject to the PRA (5 CFR 1320.3(h)(5)). Also, because of the limited number of clinical studies with small patient populations, the number of records is expected to be insignificant at this time.

Information collections in this guideline not included in tables 1 through 6 can be found under existing regulations and approved under the OMB control numbers as follows: (1) ''Current Good Manufacturing Practice for Finished Pharmaceuticals,'' 21 CFR 211.1 through 211.208, approved under OMB control number 0910–0139; (2) ''Investigational New Drug Application,'' 21 CFR 312.1 through 312.160, approved under OMB control number 0910–0014; and; (3) information included in a biologics license application, 21 CFR 601.2, approved under OMB control number 0910–0338. (Although it is possible that a xenotransplantation product may not be regulated as a biological product (e.g., it may be regulated as a medical device), FDA believes, based on its knowledge and experience with xenotransplantation, that any xenotransplantation product subject to FDA regulation within the next 3 years will most likely be regulated as a biological product.) However, FDA recognized that some of the information collections go beyond approved collections; assessments for these burdens are included in tables 1 through 6.

In table 7 of this document, FDA identifies those collection of information activities that are already encompassed by existing regulations or are consistent with voluntary standards which reflect industry's usual and customary business practice.

TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS

PHS Guideline section	Description of collection of information activity	21 CFR Section (unless otherwise stated)
2.2.1	Document offsite collaborations.	312.52
2.5	Sponsor ensures counseling patient + family + contacts.	312.62(c)
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals.	312.23(a)(7)(a) and 211.84
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention.	42 CFR 71.53
3.2.2	Document collaboration with accredited microbiology labs.	312.52
3.2.3	Procedures to ensure the humane care of animals.	9 CFR parts 1, 2, and 3 and PHS Policy [1]
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide.	AAALAC International Rules of Accreditation [2] and NRC Guide [3]
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122
3.2.6	Animal facility SOPs.	PHS Policy [1]
3.3.3	Validate assay methods.	211.160(a)
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122
3.6.2	Develop, implement, and enforce SOPs for procurement and screening processes.	211.84(d) and 211.122(c)
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c)
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6)
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 years); investigator case histories (2 years after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c)

TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS Guideline section	Description of collection of information activity	21 CFR Section (unless otherwise stated)
4.1.2	Sponsor to justify amount and type of reserve samples.	211.122
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a)
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32
4.2.2.1	Document collaborations (transfer of obligation).	312.52
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly)..	312.50
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b)

[1] The ''Public Health Service Policy on Humane Care and Use of Laboratory Animals'' (*http://www.grants.nih.gov/grants/olaw/references/phspol.htm*).
[2] AAALAC International Rules of Accreditation (*http://www.aaalac.org/accreditation/rules.cfm*).
[3] The NRC's ''Guide for the Care and Use of Laboratory Animals.''

Dated: October 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–26494 Filed 10–26–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act of 1974; System of Records

AGENCY: Department of Health and Human Services (HHS), Indian Health Service (IHS).

ACTION: Notice of New System of Records.

SUMMARY: As required by the Privacy Act of 1974, 5 U.S.C. 552a(e), notice is hereby given that the Indian Health Service (IHS) is creating a new system of records entitled ''Personal Health Records (PHR) Administrative Records—IHS'' 09–17–0005. The new system will serve as an access system, providing IHS patients with web access to a portion of their personal medical information in the IHS Medical, Health, and Billing Records system, 09–17–0001.

DATES: Comments on the new system of records must be received no later than December 13, 2012. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by the IHS, the new system will become effective on the published date of December 13, 2012.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand-delivery to the IHS Privacy Act Officer, IHS, Office of Management Services, Division of Regulatory Affairs, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852; or by fax to (301) 443–9879.

Comments received will be available for public inspection in the IHS Division of Regulatory Affairs, Room 450–26, between the hours of 9:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (301) 443–1116 (this is not a toll-free number) for an appointment. Additionally, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Christopher Lamer, PharmD, BCPS, MHS, CDE, CDR U.S. Public Health Service, Indian Health Service Nashville Area Office, Office of Information Technology/Health Education, 711 Stewards Ferry Pike, Nashville, TN 37214. Telephone number: (615) 669–2747. Email: *chris.lamer@ihs.gov.*

SUPPLEMENTARY INFORMATION:

I. Current and Future Functions of the Personal Health Records (PHR) Administrative Records—IHS System (IHS PHR)

The Personal Health Records (PHR) Administrative Records—IHS system (hereafter referred to as ''IHS PHR'') is a new web-based access system that will provide IHS patients with Internet access to a portion of their personal medical information in another IHS Privacy Act system. In its current design, the IHS PHR will provide access to information that is a subset of the already defined Department of Health and Human Services, Indian Health Service, Office of Clinical and Preventive Services (HHS/IHS/OCPS) System of Records Notice (SORN) 09–17–0001–IHS Medical, Health, and Billing Records system. The IHS PHR system will contain administrative records needed to manage patients' web access; initially, patients will be granted access to view and print portions of their official IHS electronic health record (EHR) via the Internet.

As the IHS PHR develops and eventually provides more than just ''view'' access to the current IHS Medical, Health and Billing Records system, this System of Records Notice will be updated and republished. Future IHS PHR functionality will include providing tools to the patients which they can use to: Improve their own health and increase their knowledge about health conditions; increase communication with their care providers (i.e., secure electronic messaging with their IHS health care providers); request on-line prescription refills and view upcoming appointments; and enter their own medical information in a ''self-entered'' health information section through a secure and private health space.

Initially, the IHS PHR will not provide user access to a patient's personal health information to anyone other than the patient himself or herself.

The print functionality of the IHS PHR will allow patients to share all or part of the information in their account, once the patient prints it out, with personal representatives that they designate, such as family members, legal guardians, as well as IHS and non-IHS health care providers, which is consistent with existing IHS clinical practices.

As the IHS PHR continues to be developed, it will have the ability to register and verify the identity of the patient's personal representative, in order to provide the representative with user access to the patient's records. In addition, future system enhancements will enable the IHS PHR to store the patient's self-entered information in a separate database, which will eventually have the capacity to be linked or