ESTIMATED ONE-YEAR ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Screener	Adults	2,000	1	3/60	100
Focus group discussion guide and mini-questionnaire.	Adolescents ages 13–15.	160	1	2	320
Total		2,160			420

Seleda M. Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–27881 Filed 11–19–09; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Aging the authorities vested in the Secretary of Health and Human Services under Section 1701(a)(3)(A–B), Section 1701(a)(4), and Section 1703(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(3)(A–B), 300u(a)(4), and 300u–2(a), as amended), as they pertain to the exercise of the funds transferred by the Secretary to the Administration on Aging under the ''Prevention and Wellness Fund'' of the American Recovery and Reinvestment Act of 2009, Public Law 111–5 (Feb. 17, 2009) to carry out evidence-based clinical and community-based prevention and wellness strategies through chronic disease self-management programs targeted to improving the health of seniors under the ''Communities Putting Prevention to Work'' initiative.

These authorities may be redelegated.

Exercise of these authorities is concurrent to and does not supplant existing delegations of authority from the Secretary. Exercise of these authorities shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary.

I hereby affirm and ratify any actions taken by the Assistant Secretary for Aging or his or her subordinates, which involved the exercise of the authorities delegated herein prior to the effective date of this delegation. This delegation is effective immediately.

Dated: November 12, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–27863 Filed 11–19–09; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Notice; Proposed Information Collection: Indian Health Service Forms

AGENCY: Indian Health Service, HHS.

ACTION: Request for Public Comment: 30-day Proposed Information Collection: Indian Health Service Forms to Implement the Privacy Rule (45 CFR parts 160 & 164).

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the PRA95, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval.

The IHS received no comments in response to the 60-day **Federal Register** notice (74 FR 30095) published on June 24, 2009. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–0030, ''Indian Health Service Forms to Implement the Privacy Rule (45 CFR parts 160 & 164)''. *Type of Information Collection Request:* Extension, with revisions, of currently approved information collection, 0917–0030, ''Indian Health Service Forms to Implement the Privacy Rule (45 CFR parts 160 & 164)''. *Form Number:* IHS–810, IHS–912–1, IHS–912–2, IHS–913, and IHS–917. *Need and Use of Information Collection:* The IHS will use the following data collection instructions to continue the implementation of the information collection requirements contained in the Privacy Rule.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, directly to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Allison Eydt, Desk Officer for IHS.

For Further Information: Send requests for more information on the proposed collection or to obtain a copy of the data collection instrument(s) and instructions to: Ms. Betty Gould, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1601, call non-toll free (301) 443–7899, send via facsimile to (301) 443–9879, or send your e-mail requests, comments, and return address to: *betty.gould@ihs.gov.*

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: November 6, 2009.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. E9–27541 Filed 11–19–09; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0556]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs; Proposed New Data Elements for Adverse Event Reports on Revised Forms FDA 1932 and 1932a

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 and to allow for public comment in response to the notice. This notice solicits comments on requirements for recordkeeping and reports concerning experience with approved new animal drugs, specifically on new data elements to be used in revised versions of Forms FDA 1932 and 1932a. The information contained in the reports required by this regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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, Office of Management Programs (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION:

I. Background

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 notice in the **Federal Register** concerning each proposed 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.

II. Records and Reports Concerning Experience With Approved New Animal Drugs; Proposed New Data Elements for Adverse Event Reports on Revised Forms FDA 1932 and 1932a; 21 CFR 514.80 (OMB Control No. 0910–0645)—Revision

Section 512(l) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360b(l)) and § 514.80(b) of FDA regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

An applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs'' (see § 514.80(d)). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

Collection of information using existing paper forms FDA 2301, 1932, and 1932a is currently approved under OMB control number 0910–0284, set to expire on January 31, 2010. FDA currently is seeking renewal of that information collection.

FDA recently proposed to collect information using electronic versions of Forms FDA 1932 and 1932a as part of the agency-wide information collection (MedWatch^{Plus} Portal and Rational Questionnaire) that was announced for public comment in the **Federal Register** on October 23, 2008 (73 FR 63153). The MedWatch^{Plus} Portal and Rational Questionnaire are components of a new electronic system for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products.

In this 30-day notice, FDA is requesting public comment on data elements associated with revisions to forms FDA 1932 and 1932a (both paper and electronic) under revised OMB control number 0910–0645, described below. We will publish separately in the **Federal Register** a 30-day notice to complete the renewal of OMB control number 0910–0284, the collection of information using existing paper forms FDA 2301, 1932, and 1932a, to provide time for development of the revised FDA Forms 1932 and 1932a and their incorporation into the MedWatch OMB