TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
1.101(d) (Non-Tobacco products)	73	503	36,719	15	550,785

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.101(b), (c), and (e) (Non-Tobacco Products)	320	3	960	22	21,120
1.101(b) (Non-Tobacco Products for Office of International Programs only)	1	189	189	22	4,158
1.101(b) (Tobacco Products Only)	158	3	474	22	10,428
Total					35,706

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

Dated: June 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15647 Filed 7–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0307]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antiparasitic Drug Use and Antiparasitic Resistance Survey

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 August 4, 2014.

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–NEW and title ''Antiparasitic Drug Use and Antiparasitic Resistance Survey.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Antiparasitic Drug Use and Antiparasitic Resistance Survey—21 CFR 514.4 (OMB Control Number—0910–NEW)

Resistance of parasites to one or more of the major classes of FDA-approved antiparasitic drugs is a documented problem in cattle, horses, sheep, and goats in the United States. The results from this survey will provide FDA information that can be used to make decisions about future approaches to antiparasitic drugs. FDA will make the results of the survey publicly available.

FDA's Center for Veterinary Medicine (CVM) plans to survey members of veterinary professional organizations using an Internet-based survey instrument. The questions in the survey are designed to elicit professional opinions regarding the use of antiparasitic drugs and the awareness of antiparasitic drug resistance. The survey will query subjects on topics including: (1) Awareness of the issues related to antiparasitic drug resistance; (2) methods currently being used to detect and/or monitor for antiparasitic drug resistance; (3) management practices being used or recommended to manage or reduce antiparasitic drug resistance; and (4) labeling and marketing considerations for antiparasitic drugs.

In the **Federal Register** of December 3, 2012 (77 FR 71603), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received several comments in response to the notice, which are discussed below.

(Comment) The first comment stated that the collection is not necessary for the proper performance of FDA's functions.

(CVM Response) We disagree. The mission of the Office of New Animal Drug Evaluation within CVM is to expeditiously approve safe and effective, properly labeled, quality manufactured new animal drugs through a science-based approach in a regulatory environment. This collection is necessary for the proper performance of FDA/CVM's mission because it will help us gather information that can be used to appropriately label antiparasitic drugs and, thereby, enhance the sustainability and continued availability of approved antiparasitic drugs.

(Comment) Another comment stated that while assessing the current situation in the field is important, the information to be gained from the survey will have little practical utility because the data will be of opinions held by an extremely small sample size.

(CVM Response) The target population for this survey is the subset of veterinarians and parasitologists who have a direct opportunity to observe and assess the antiparasitic resistance issues in the field. CVM understands that a part of the target population, namely

veterinarians with training and experience with large animals, are diminishing in numbers in some areas of the United States (*https://www.avma.org/KB/Resources/Reference/Pages/Food-Supply-Veterinary-Medicine-Data-Maps.aspx*). While a wider and more general sampling of veterinarians would provide a larger sample size, such sampling would then include those who have opinions on the topic of antiparasitic resistance but not direct experience with the animal populations of interest. CVM designed the survey with input from subject matter experts, statisticians, and epidemiologists to reach the largest and most representative sample of this target population. Sample size, as well as total survey error, was considered in the design.

(Comment) One comment stated that there are numerous variables involved in the field; thus, measuring resistance by observational methods has questionable validity. Re-infection is a significant confounder which could mimic resistance. Resistance should be determined more scientifically, such as through a challenge model.

(CVM Response) The survey is not designed to measure antiparasitic resistance but to collect information from clinical experts who diagnose and treat the relevant animal populations and to provide a basis to assist in the design of labeling for approved antiparasitic drug products and the design of educational outreach programs. Data from laboratory-based, experimental models is extremely important for characterizing antiparasitic resistance. For successful translational research, both ''bench'' research, such as challenge models, and research from clinical or field settings, such as collecting the observations of clinicians treating and monitoring real animal patients are needed (*http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=045-578*).

(Comment) One comment stated that many antiparasitic drugs are available as over-the-counter drugs. Inappropriate or inconsistent administration could produce a perceived resistance.

(CVM Response) CVM has not designed the survey to estimate the prevalence of resistance and agrees with the comment that the survey should not be used to draw conclusions about potential causes of resistance. The collection of such data would require a multiyear, multisite study of parasite resistance and antiparasitic drug use in multiple species in diverse geographic regions throughout the country. Such a study would be prohibitively expensive and complicated and is outside the scope of this survey. However, the survey is appropriately designed to gauge the level of awareness and concern about antiparasitic drug resistance issues among veterinarians using drugs in different clinical practice and production settings, as well as among academic parasitologists and scientists involved in drug research and development. In addition, the survey is designed to investigate methods currently used by veterinarians to detect, monitor, and manage parasites and antiparasitic drug resistance.

(Comment) Another comment suggested FDA's efforts regarding drug safety and efficacy are vital. The survey could potentially yield a small glimpse of conditions in the field; however, the information to be gathered seems to be an ill fit with postmarket surveillance as well as adverse event reporting.

(CVM Response) We agree that the survey should not attempt to obtain the same data as that obtained through postmarket surveillance and adverse event reporting. The survey is not designed to yield data or reports of adverse drug reactions, lack of effectiveness, or product defects which is obtained as part of postmarket surveillance. Information regarding the current state of awareness and concern about antiparasitic drug resistance issues in the field is important because it will assist CVM in the enhancement of appropriate labeling for the safe and effective use of approved antiparasitic drug products. The survey is one tool in a comprehensive antiparasitic resistance management strategy within CVM aimed at facilitating collaboration with CVM stakeholders on the issues related to antiparasitic resistance.

(Comment) Another comment stated that recommendations regarding the management or reduction of antiparasitic resistance are aspects of medical management and preventative herd health within the practice of veterinary medicine. Such recommendations are based upon veterinary expertise combined with several factors including animal owner capabilities, animal species and health, and the parasitic risks. The respondent questioned FDA's reasoning and intended regulatory use in gathering such information from responders, especially since such recommendations are available in scientific literature.

(CVM Response) The proposed survey is not intended as a replacement for the review of scientific research in published literature or the recommendations of expert veterinary parasitologists. As announced for the ''Antiparasitic Drug Use and Resistance in Ruminants and Equines; Public Meeting; Request for Comments'' (77 FR 7588, February 13, 2012; Docket No. FDA–2012–N–0102), CVM is committed to accessing and highlighting current research associated with the development and management of antiparasitic resistance in the United States. The survey is not designed to lead to any new recommendations regarding the management or reduction of antiparasitic resistance or provide recommendations related to the practice of veterinary medicine, but rather obtain information regarding the awareness and use of a variety of available strategies for detecting, monitoring, and/or managing antiparasitic resistance. CVM will not use the survey to undermine efforts of other organizations to provide science-based recommendations regarding the management or reduction of antiparasitic resistance. Instead, information obtained from the survey will be used to ensure properly labeled, safe, and effective antiparasitic drugs are available to veterinarians. In doing so, CVM will be providing the best array of options for veterinarians to choose from as they serve their patients and will be fulfilling its mission to protect human and animal health.

(Comment) Finally, one comment suggested that if a survey is to be done, it should be redesigned so that, while it may still gather opinions, it focuses on obtaining pertinent scientific information and more accurately targets respondents possessing the appropriate expertise on this particular subject. Also, that the incorporation of a scientific literature review may be beneficial in addressing some of the questions proposed.

(CVM Response) CVM believes that there are other more appropriate ways to obtain specific scientific information regarding antiparasitic resistance, such as holding public meetings, directly consulting with experts in the field of veterinary parasitology, and reviewing published literature available on the subject. As previously discussed, this survey is designed specifically to obtain information on the levels of awareness and concern related to antiparasitic resistance issues among veterinarians, key stakeholders for CVM.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-test	7	1	7	.5 (30 minutes).	3.5
Survey	650	1	650	.5 (30 minutes).	325
Total					328.5

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

FDA calculated the total annual responses by multiplying the number of respondents by the annual frequency. FDA calculated the total hours by multiplying the estimated hours per response by the number of respondents.

Dated: June 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15648 Filed 7–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; Tribal Management Grant Program

Announcement Type: New and Competing Continuation.

Funding Announcement Number: HHS–2014–IHS–TMD–0001.

Catalog of Federal Domestic Assistance Number: 93.228.

Key Dates

Application Deadline Date: August 5, 2014.

Review Date: August 18, 2014.

Earliest Anticipated Start Date: September 15, 2014.

Signed Tribal Resolutions Due Date: August 15, 2014.

Proof of Non-Profit Status Due Date: August 15, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive grant applications for the Tribal Management Grant (TMG) program. This program is authorized under 25 U.S.C. 450h(b)(2) and 25 U.S.C. 450h(e) of the Indian Health Self-Determination and Education Assistance Act (ISDEAA), Public Law (Pub. L.) 93–638, as amended. This program is described in the Catalog of Federal Domestic Assistance under 93.228.

Background

The TMG Program is a competitive grant program that is capacity building and developmental in nature and has been available for Federally-recognized Indian Tribes and Tribal organizations (T/TO) since shortly after the passage of the ISDEAA in 1975. It was established to assist T/TO to assume all or part of existing IHS programs, functions, services, and activities (PFSA) and further develop and improve their health management capability. The TMG Program provides competitive grants to T/TO to establish goals and performance measures for current health programs; assess current management capacity to determine if new components are appropriate; analyze programs to determine if T/TO management is practicable; and develop infrastructure systems to manage or organize PFSA.

Purpose

The purpose of this IHS grant announcement is to announce the availability of the TMG Program to enhance and develop health management infrastructure and assist T/TO in assuming all or part of existing IHS PSFA through a Title I contract and assist established Title I contractors and Title V compactors to further develop and improve their management capability. In addition, TMGs are available to T/TO under the authority of 25 U.S.C. 450h(e) for: (1) Obtaining technical assistance from providers designated by the T/TO (including T/TO that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management and the development of cost allocation plans for indirect cost rates; and (2) the planning, designing, monitoring, and evaluation of Federal programs serving the T/TO, including Federal administrative functions.

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2014 is approximately $1,412,000. Individual award amounts are anticipated to be between $50,000 and $100,000. The amount of funding available for both competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 16–18 awards will be issued under this program announcement.

Project Period

The project periods vary based on the project type selected. Project periods could run from one, two, or three years and will run consecutively from the earliest anticipated start date of September 15, 2014 through September 14, 2015 for one year projects; September 15, 2014 through September 14, 2016 for two year projects; and September 15, 2014 through September 14, 2017 for three year projects. Please refer to ''Eligible TMG Project Types, Maximum Funding Levels and Project Periods'' below for additional details. State the number of years for the project period and include the exact dates.

III. Eligibility Information

1. Eligibility

Eligible Applicants: ''Indian Tribes'' and ''Tribal organizations'' (T/TO) as defined by the ISDEAA are eligible to apply for the TMG Program. The definitions for each entity type are outlined below. Only one application per T/TO is allowed.

Definitions: ''Indian Tribe'' means any Indian tribe, band, nation, or other