facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the state at the hearing.

Sincerely,

Marilyn Tavenner,
Administrator.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: June 27, 2014.

Marilyn Tavenner,

Administrator, Center for Medicare & Medicaid Services.

[FR Doc. 2014–15615 Filed 7–2–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exports: Notification and Recordkeeping Requirements

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 (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 export notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, cosmetics, and tobacco that may not be marketed or sold in the United States.

DATES: Submit either electronic or written comments on the collection of information by September 2, 2014.

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: 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: 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.

Exports: Notification and Recordkeeping Requirements—21 CFR 1.101 (OMB Control Number 0910–0482)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring exports (Exports: Notification and Recordkeeping Requirements—§ 1.101 (21 CFR 1.101)) which pertain to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products are not be sold in the United States.

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or markets in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods, cosmetics, and tobacco products that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

On March 30, 2012, OMB approved ''Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products,'' OMB control number 0910–0690, which amended, among other sections, § 1.101 to incorporate tobacco products. This amendment reflects the Agency's authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) and added tobacco products to the list of products covered under § 1.101(a) and (b).

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

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