reporting on the overall performance of these grant programs.

Data will be collected from all 60 Community-Centered Healthy Marriage, 54 Pathways to Responsible Fatherhood and 5 Community-Centered Responsible Fatherhood Ex-Prisoner Reentry grantees in the OFA programs. Grantees will report on program and participant outcomes in such areas as participants' improvement in knowledge skills, attitudes, and behaviors related to healthy marriage and responsible fatherhood. Grantees will be asked to input data for selected outcomes for activities funded under the grants. Grantees will extract data from program records and will report the data twice yearly through an on-line data collection tool. Training and assistance will be provided to grantees to support this data collection process.

Respondents: Office of Family Assistance Funded Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Performance measure reporting form (for private sector affected public)	110	2	0.8	176
Performance measure reporting form (for State, local, and tribal government affected public)	9	2	0.8	14

Estimated Total Annual Burden Hours: 190

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–15547 Filed 6–24–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Request for Nominations; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''List of Bulk Drug Substances That May Be Used by an Outsourcing Facility to Compound Drugs for Use in Animals; Request for Nominations'' that appeared in the **Federal Register** of May 19, 2015 (80 FR 28622). The document announced the intention to develop a list of bulk drug substances that may be used by outsourcing facilities registered under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs, in accordance with FDA's draft guidance for industry #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, May 19, 2015, in FR Doc. 2015–11983, the following correction is made:

1. On page 28622, in the second column, in the **ADDRESSES** section of the document, under *Instructions,* ''Docket No. FDA–2013–N–1524'' is corrected to read ''Docket No. FDA–2015–N–1196''.

Dated: June 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15558 Filed 6–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0915]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

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.

DATES: Fax written comments on the collection of information by July 27, 2015.

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 0910–0636. 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.

Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (OMB Control Number 0910–0636)—Extension

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) (21 U.S.C. 352(b)(1)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States. FDA is requesting public comment on estimates of annual submissions from these respondents, as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462) and described in the guidance. The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) (21 U.S.C. 379aa(b)(1)) of the FD&C Act, including follow-up reports under 760(c)(2) (21 U.S.C. 379aa(c)(2)) of the FD&C Act, and how to submit these reports. The estimates for the annual reporting and recordkeeping burdens are based on FDA data on the number of adverse drug experience reports submitted for nonprescription drug products marketed without an approved application, including FDA's knowledge about the time needed to prepare the reports and to maintain records.

In the **Federal Register** of January 23, 2015 (80 FR 3608), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The comment requested that we increase the reporting burden estimates from 2 hours to 6 hours and the recordkeeping burden estimates from 5 hours to 8 hours. The comment said although there may be circumstances where FDA's estimates for reporting and recordkeeping may be accurate, the comment contended that, in its experience, the approximations are underestimated. The comment said that as many as 6 hours may be required to complete a single serious adverse event report, especially when the sponsor's medical and quality review teams are involved, and that as many as 8 hours may be required to maintain all relevant records for a single adverse event report as stipulated by statute.

FDA Response: We have reconsidered our estimates, and agree with the comment that there may be circumstances where 6 hours would be needed to prepare and submit a report to us and 8 hours may be needed for recordkeeping. We have revised our reporting and recordkeeping burden estimates accordingly.

Based on FDA data, we estimate between 10,000 and 15,000 (*i.e.,* approximately 12,500) total annual responses from approximately 50 respondents for nonprescription drugs marketed without an approved application, and we also estimate that each submission will take approximately 6 hours to prepare and submit.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports of serious adverse drug events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	6	75,000

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

Section 760(e) (21 U.S.C. 379aa(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance document recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any follow-up reports. We estimate that there are approximately 20,000 records per year maintained by approximately 200 respondents, and that it takes approximately 8 hours to maintain each record.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	8	160,000

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

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15638 Filed 6–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2163]

Agency Information Collection Activities; Proposed Collection; Comment Request; Hearing, Aging, and Direct-to-Consumer Television Advertisements

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 60 days for public comment in response to the notice. This notice solicits comments on research entitled, ''Hearing, Aging, and Direct-to-Consumer Television Advertisements''. This study will examine how changes to hearing across the lifespan affect the comprehension of direct-to-consumer (DTC) television advertisements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by August 24, 2015.

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 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.

Hearing, Aging, and Direct-to-Consumer Television Advertisements—(OMB Control Number 0910–NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Older adults use a disproportionate number of prescription drugs (Ref. 1) and watch more television than other age groups (Ref. 2). Age-related changes in hearing are common (Ref. 3, 4, and 5) and, depending on their severity, influence the understanding of speech. DTC television advertisements (ads) contain large amounts of complex information about prescription drug treatments that may be particularly relevant to a population that is experiencing some level of hearing loss. Moreover, much of the information in these ads is conveyed by voiceover, meaning that the audio channel is the only way to receive the information. Although people with serious hearing loss may compensate by using closed captioning (which may or may not be available for ads) or hearing aids, some individuals experience the effects of hearing loss without realizing that it is the cause and others choose not to use external compensatory aids (Ref. 6). For these reasons, FDA is proposing research to investigate how people at various ages and levels of hearing ability comprehend DTC ads.

Sponsors of DTC ads cannot control the hearing abilities of their audiences. Nonetheless, researchers have identified several aspects of DTC ads within their control that influence the understanding of speech in individuals who experience aging-related hearing loss. First, frequency thresholds differ as people age; older adults are not able to hear higher frequencies as well (Ref. 7 and 8). Second, DTC television ads contain a risk statement of the most serious and most common side effects, called ''the major statement''. FDA regulations require that the major statement must be included in at least the audio portion of the ad (Ref. 9). The risks of a medical product often include highly technical medical terms that must be transformed into consumer-friendly language to convey the risks appropriately. This is easier in some cases than in others. In addition, there are techniques to help reduce the complexity of the major statement, such as maintaining active voice, reducing instances where words need clarification from other later words in the broadcast, and using shorter sentences. Third, television ad spots are typically bought in increments of 15 seconds, leading to many 30- and 60-second ads, and some 75-second ads when risk information is especially dense. In order to fit the required information into this time frame, the audio presentation speed may be adjusted to be faster or slower. Research has shown that fast speech is more difficult to understand than slower speech, even for healthy young adults (Ref. 10).

Thus, we propose to examine the effects of three aspects of DTC ads (voice frequency, complexity of major statement, speed of major statement) on the comprehension of the ads among four different age groups of individuals. Because hearing losses begin to occur as people age, we will examine a group of middle-aged adults (40–50 years), young-old adults (60–75 years), and old-old adults (75+ years), and a group of