proprietary loans, this would meet the PRA's definition of paperwork burden.

There are also additional provisions in the guidance that apply to both proprietary and HECM reverse mortgages that do not meet the ''usual and customary'' standard, are not covered by already approved information collections and, therefore, likewise meet the PRA's definition of paperwork burden.

Proprietary Reverse Mortgages

Financial institutions offering proprietary reverse mortgages are encouraged under the guidance to follow or adopt relevant HECM requirements for mandatory counseling, disclosures, affordable origination fees, restrictions on cross-selling of ancillary products, and reliable appraisals.

Proprietary and HECM Reverse Mortgages

Financial institutions offering either proprietary or HECM reverse mortgages are encouraged to develop clear and balanced product descriptions and make them available to consumers shopping for a mortgage. They should set forth a description of how disbursements can be received and include timely information to supplement disclosures mandated by TILA and other disclosures. Promotional materials and product descriptions should include information about the costs, terms, features, and risks of reverse mortgage products.

Financial institutions should adopt policies and procedures that prohibit directing a consumer to a particular counseling agency or contacting a counselor on the consumer's behalf. They should adopt clear written policies and establish internal controls specifying that neither the lender nor any broker will require the borrower to purchase any other product from the lender in order to obtain the mortgage. Policies should be clear so that originators do not have an inappropriate incentive to sell other products that appear linked to the granting of a mortgage. Legal and compliance reviews should include oversight of compensation programs so that lending personnel are not improperly encouraged to direct consumers to particular products.

Financial institutions making, purchasing, or servicing reverse mortgages through a third party should conduct due diligence and establish criteria for third-party relationships and compensation. They should set requirements for agreements and establish systems to monitor compliance with the agreement and applicable laws and regulations. They should also take corrective action if a third party fails to comply. Third-party relationships should be structured in a way that does not conflict with RESPA.

Board of Governors of the Federal Reserve System, June 18, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–15412 Filed 6–22–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0481]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Uses

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 23, 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 0910–0117. 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.

New Animal Drugs for Investigational Uses—21 CFR Part 511

OMB Control Number 0910–0117—Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to approve new animal drugs. Section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511. If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational new animal drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse. The Agency uses these required records under its Bioresearch Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions. Respondents to this collection of information are the persons who use new animal drugs for investigational purposes.

In the **Federal Register** of April 2, 2015 (80 FR 17758), FDA published a 60-day notice requesting public comment on the proposed collection of

information. Two comments were received but neither responded to any of the four information collection topics solicited and are therefore not addressed by the Agency.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4)	263	5.30	1,395	1	1,395
511.1(b)(5)	263	.26	69	8	552
511.1(b)(6)	263	.01	2	1	2
511.1(b)(8)(ii)	263	.06	15	2	30
511.1(b)(9)	263	.06	15	8	120
Total					2,099

[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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3)	263	2.07	545	1	545
511.1(b)(3)	263	5.30	1,395	1	1,395
511.1(b)(7)(ii)	263	5.30	1,395	3.5	4,882.5
511.1(b)(8)(i)	263	5.30	1,395	3.5	4,882.5
Total					11,705

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on informal Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 263 respondents. We use this estimate consistently throughout the table and calculate the ''annual frequency per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from Agency records.

Dated: *June 17, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15320 Filed 6–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0253]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Drug Experience Reporting and Recordkeeping Biological Products

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 22, 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 0910–0230. 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.

Postmarketing Adverse Drug Experience Reporting

OMB Control Number 0910–0230—(Extension)

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences associated with the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that