Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use:* The current generic clearance for MCBS Questionnaire Testing and Methodological Research encompasses development and testing of MCBS questionnaires, instrumentation, and data collection protocols, as well as a mechanism for conducting methodological experiments. The current clearance includes conducting field tests and experiments, including split ballot experiments, within the MCBS production environment, and conducting usability tests. The purpose of this OMB clearance package is to revise the current clearance to expand the methods to allow for field tests outside of MCBS production Field tests conducted within production do not incur any additional burden on respondents whereas tests conducted outside production must account for additional respondent burden. The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS, which is sponsored by the Centers for Medicare & Medicaid Services (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. The core of the MCBS is a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees, residing in the community or in institutions. Questions are asked about enrollees' patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, the MCBS collects information on special topics. *Form Number:* CMS–10549 (OMB control number: 0938–1275); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 11,655; *Total Annual Responses:* 11,655; *Total Annual Hours:* 3,947. (For policy questions regarding this collection, contact William Long at 410–786–7927.)

Dated: December 17, 2020.

William N. Parham III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–28224 Filed 12–22–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 veterinary feed directive regulation.

DATES: Submit either electronic or written comments on the collection of information by February 22, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 22, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0155 for ''Veterinary Feed Directive.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Veterinary Feed Directive

OMB Control Number 0910–0363—Extension

Section 504 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called veterinary feed directive (VFD) drugs. The VFD regulation is set forth at § 558.6 (21 CFR 558.6). VFD drugs are new animal drugs, intended for use in or on animal feed, which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice (§ 558.6(b)(6)). An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian (§ 558.6(a)(1)).

Veterinarians issue three copies of the VFD: One for their own records, one for their client, and one to the client's VFD feed distributor (§ 558.6(a)(4) and (b)(8) and (9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs (§ 558.6(b)(3)), along with other information required under § 558.6. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs.

The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible. The VFD regulation is tailored to the unique circumstances relating to the distribution and use of animal feeds containing a VFD drug.

We will use the information collected to assess compliance with the VFD regulation. The required recordkeeping and third-party disclosures provide assurance that the medicated feeds will be safe and effective for their labeled conditions of use and that edible products from treated animals will be free of unsafe drug residues.

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors and VFD Drug Sponsors.

A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes the VFD feed (§ 558.6(c)(5)). This notification is required one time per distributor and must include the information set forth in § 558.6(c)(5). In addition, a distributor must notify FDA within 30 days of any change in ownership, business name, or business address (§ 558.6(c)(6)). Additional reporting burdens for current VFD drug sponsors are approved under OMB control numbers 0910–0032 (New Animal Drug Application) and 0910–0669 (Abbreviated New Animal Drug Applications).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(c)(5) requires a distributor to notify FDA prior to the first time it distributes a VFD feed.	188	1	188	0.125 (7 minutes)	24
558.6(c)(6) requires a distributor to notify FDA within 30 days of any change in ownership, business name, or business address.	192	1	192	0.125 (7 minutes)	24
Total					48

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

B. Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

As stated previously, veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor. All involved parties (veterinarian, distributor, and client) must retain a copy of the VFD for 2 years (§ 558.6(a)(4)). In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for inspection by FDA for 2 years (§ 558.6(c)(3)). If a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with 21 CFR part 225 and such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, ''Current Good Manufacturing Practice Regulations for Medicated Feed. '' Distributors may distribute VFD feeds to another distributor only if the originating distributor (consignor) first obtains a written acknowledgment letter from the receiving distributor (consignee) before the feed is shipped. Such letters, like VFDs, are also subject to a 2-year record retention requirement (§ 558.6(c)(8)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(a)(4); required recordkeeping by veterinarians and producers.	13,050	114.9	1,500,000	0.0167 (1 minute)	25,050
558.6(a)(4), (c)(3), (4), and (8); required recordkeeping by distributors.	9,635	545.1	5,252,038	0.0167 (1 minute)	87,709
Total					112,759

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

C. Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients.

FDA regulation requires that veterinarians include the information specified at § 558.6(b)(3) through (5) on the VFD. Additional requirements relating to the VFD are specified at § 558.6(b)(7) through (9). A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgment letter from the receiving distributor (consignee) before the feed is shipped (§ 558.6(c)(8)).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)–(5) and (b)(7)–(9); required disclosures when a veterinarian issues a VFD.	3,050	246	750,000	0.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgment letter) from one distributor to another.	1,000	5	5,000	0.125 (7 minutes)	625
Total					94,375

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

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian'' (§ 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (§ 558.6(b)(3)(xiii)): ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted. ''

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (§ 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs'' (§ 558.6(b)(6)(i)).

2. ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component. '' (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.) (§ 558.6(b)(6)(ii)).

3. ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component'' (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*).

Based on a review of the information collection since our last request for OMB approval, there has been a significant increase in the number of VFD distributors due to changes to the VFD regulations that were implemented in 2017. Since implementation, the number of approved VFD drugs has increased.

Dated: December 17, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28353 Filed 12–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by January 22, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Orphan Drugs

OMB Control Number 0910–0167—Revision

This information collection supports FDA regulations implementing sections 525, 526, 527, and 528 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360aa, 360bb, 360cc, and 360dd), as well as related guidance. Sections 525, 526, 527, and 528 of the FD&C Act pertain to the development of drugs for rare diseases or conditions, including biological products and antibiotics, otherwise known or referred to as ''Orphan Drugs.'' Specifically, section 525 of the FD&C Act requires written recommendations on studies required for approval of a marketing application for a drug for a rare disease or condition. The information collection in 21 CFR 316.10, 316.12, and 316.14 is approved under OMB control numbers 0910–0001 and 0910–0014. Section 526 of the FD&C Act provides for designation of drugs as orphan drugs when certain conditions are met, section 527 provides conditions under which a sponsor of an approved orphan drug enjoys exclusive FDA marketing approval for that drug for the orphan indication for a period of 7 years, and, finally, section 528 is intended to encourage sponsors to make investigational orphan drugs available for treatment of persons in need on an open protocol basis before the drug has been approved for general marketing. Open protocols may permit patients who are not part of the formal clinical investigation to obtain treatment where adequate supplies exist and no alternative effective therapy is available.

We have issued regulations in part 316 (21 CFR part 316) to implement the Orphan Drug provisions of the FD&C Act and to set forth procedures and requirements related to requesting recommendations for investigations of drugs for rare diseases or conditions, requesting designation of a drug for a rare disease or condition, or requesting exclusive approval for a drug for a rare disease or condition. To assist respondents and to be consistent with § 316.50, our Office of Orphan Products Development (OOPD) maintains and makes publicly available guidance documents that apply to the Orphan Drug provisions of the FD&C Act and regulations in part 316. The list is maintained on the internet and guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Accordingly, we are revising the information collection to include Agency guidance. The document entitled ''Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff'' provides recommendations to industry, researchers, patient groups, and other stakeholders interested in requesting a meeting, including a teleconference, with OOPD on issues related to orphan drug designation requests, humanitarian use device designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. It is also intended to assist OOPD staff in addressing such meeting requests. This guidance describes procedures for requesting, preparing, scheduling, conducting, and documenting such meetings and discusses background information we recommend be included in such requests. Information collection attendant to recommendations in the guidance are currently approved under OMB control number 0910–0787; however, for efficiency of Agency operations, we are consolidating it into this related information collection. The guidance is available at *https://www.fda.gov/media/92815/download*.

The FDA Orphan Drug Designation Request Form (Form FDA 4035) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from only FDA. The form is a simplified