received an order under section 911(g)(2) of the FD&C Act [1] as an MRTP and is including information from the authorized MRTPA by cross-reference.

FDA will post the application documents, including those cross-referenced from prior submissions previously authorized and those contained in any amendments, for public comment in batches on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 45 days after the date this notice publishes and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the relatively low volume of information in the MRTPA that has not already been available for public comment as part of the previously authorized MRTPAs for the IQOS system. FDA will notify the public about the availability of application documents and comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the **Federal Register** regarding the availability of additional application documents, including amendments, or the comment period for this MRTPA. To receive email alerts, visit FDA's email subscription service management website (*https://www.fda.gov/about-fda/contact-fda/get-email-updates*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Update'', and click ''Submit''. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPA that is the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may obtain the application documents at either *https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications* or *http://www.regulations.gov.*

Dated: May 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10177 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

[1] The notice of availability for the IQOS MRTPAs that received a modified risk granted order appeared in the **Federal Register** of June 15, 2017 (82 FR 27487), and the docket containing notices and public comments, FDA–2017–D–3001, is accessible at: *https://www.regulations.gov/docket/FDA-2017-D-3001/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 14, 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 0910–0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

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.

In the **Federal Register** of December 23, 2020 (85 FR 83968), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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 Applications) 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	0.117 (7 minutes) ..	22
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	0.117 (7 minutes) ...	22
Total	.....	.....	.....	.....	44

[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 record-keeping by distributors.	9,635	545.1	5,252,039	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	750,300	0.117 (7 minutes) ..	87,785
558.6(c)(8); required disclosure (acknowledgment letter) from one distributor to another.	1,000	5	5,000	0.117 (7 minutes) ...	585

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

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Total	.....	.....	.....	.....	88,370

[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. As a result, the burden for the information collection has increased 69,148 hours since the last OMB approval.

Since the publication of the 60-day notice, we have adjusted 7 minutes for the average burden per response from 0.125 to 0.117. We believe this is a better representation for 7 minutes. As a result, this has slightly changed the burden hours.

Dated: May 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10245 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Eleventh Meeting of the National Clinical Care Commission; Correction

AGENCY: Office on Women's Health, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Office of the Assistant Secretary for Health published a document in the **Federal Register** of May 4, 2021, concerning a virtual meeting of the National Clinical Care Commission. The date of the eleventh meeting of the Commission has changed. The original dates for the eleventh meeting were May 19 and June 1, 2021. The new dates for the two-day meeting are June 1 and June 22, 2021.

FOR FURTHER INFORMATION CONTACT: Kara Elam, Ph.D., MPH, MS, Designated Federal Officer, National Clinical Care Commission, U.S. Department of Health and Human Services, Office on Women's Health, 200 Independence Ave. SW, 7th Floor, Washington, DC 20201, Phone: (240) 435–9438, Email: *Kara.Elam@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 4, 2021, FR Doc. 2021–09277, page 23731, in the first column, correct the **SUMMARY** caption to read:

SUMMARY: The National Clinical Care Commission (the Commission) will conduct its eleventh meeting virtually on June 1 and June 22, 2021. The Commission is charged to evaluate and make recommendations to the U.S. Department of Health and Human Services (HHS) Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to diabetes and its complications.

Correction

In the **Federal Register** of May 4, 2021, FR Doc. 2021–09277, page 23731, in the first column, correct the **DATES** caption to read:

DATES: The two-day meeting will take place June 1 and June 22, 2021 from 1 p.m. to approximately 6 p.m. Eastern Time (ET).

Dated: May 4, 2021.

Dorothy A. Fink,

Deputy Assistant Secretary for Women's Health.

[FR Doc. 2021–10258 Filed 5–13–21; 8:45 am]

BILLING CODE 4150–32–P