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 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)(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)(ii)).

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.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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

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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).


Dorothy A. Fink,
Deputy Assistant Secretary for Women’s Health.

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