

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

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)–(b)(5) and (b)(7)–(b)(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 (acknowledgement letter) from one distributor to another.	1,000	5	5,000	0.125 (7 minutes) .....	625
Total .....	.....	.....	.....	.....	94,375

<sup>1</sup> 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.*).

The one-time burdens included in FDA’s analysis of the June 3, 2015, final rule (80 FR 31708 at 31729 to 31732) are not included in the estimate provided in this notice. FDA’s estimate of the annual recurring burden for this information collection has not changed since the last OMB approval.

Dated: June 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–12448 Filed 6–8–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–1768]

#### Advisory Committee; Pharmacy Compounding Advisory Committee, Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Pharmacy Compounding Advisory Committee by the Commissioner of Food and Drugs (the

Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 25, 2020.

**DATES:** Authority for the Pharmacy Compounding Advisory Committee will expire on April 25, 2020, unless the Commissioner formally determines that renewal is in the public interest.

#### FOR FURTHER INFORMATION CONTACT:

Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (the Committee). The committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of

pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this Committee serve as Special Government Employees. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm381305.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1725]

#### Advisory Committee; Peripheral and Central Nervous System Drugs Advisory Committee; Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Peripheral and Central Nervous System Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Peripheral and Central Nervous System Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 4, 2020.

**DATES:** Authority for the Peripheral and Central Nervous System Drugs Advisory Committee will expire on June 4, 2020, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Yinghua Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002; 301-796-9001, email: [PCNS@fda.hhs.gov](mailto:PCNS@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Peripheral and Central Nervous System Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Peripheral and Central Nervous System Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of

voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/default.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-P-0327]

#### Determination That MUTAMYCIN (Mitomycin) Injectable, 5 Milligrams/Vial and 20 Milligrams/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that MUTAMYCIN (mitomycin) injectable, 5 milligrams (mg)/vial and 20 mg/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Stacy Kane, Center for Drug Evaluation