

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.*

[FR Doc. 2018-12440 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-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

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, [Stacy.Kane@fda.hhs.gov](mailto:Stacy.Kane@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, is the subject of NDA 050450, held by Bristol Laboratories Inc., and initially approved on May 28, 1974. MUTAMYCIN has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, is currently listed in the

“Discontinued Drug Product List” section of the Orange Book.

Fresenius Kabi USA, LLC submitted a citizen petition dated January 22, 2018 (Docket No. FDA-2018-P-0327), under 21 CFR 10.30, requesting that the Agency determine whether MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MUTAMYCIN (mitomycin) injectable, 5 mg/vial and 20 mg/vial, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-12441 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-1728]

#### Advisory Committee; Drug Safety and Risk Management 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 Drug Safety and Risk Management 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 Drug Safety and Risk Management Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 31, 2020.

**DATES:** Authority for the Drug Safety and Risk Management Advisory Committee will expire on May 31, 2018, unless the Commissioner formally determines that renewal is in the public interest.

#### FOR FURTHER INFORMATION CONTACT:

Philip Bautista, 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, [DSARM@fda.hhs.gov](mailto:DSARM@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 Drug Safety and Risk Management Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Drug Safety and Risk Management 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 information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner regarding the scientific and medical evaluation of all