

establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) into law, which included MoCRA. Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing. Section 607(a) of the FD&C Act (21 U.S.C. 364c(a)) requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA no later than 1 year after the date of enactment. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA “a cosmetic product listing.” Certain small businesses, as defined in section 612 of the FD&C Act (21 U.S.C. 364h), are exempt from the registration and listing requirements.

In the **Federal Register** of August 8, 2023 (88 FR 53490), we made available a draft guidance for industry entitled “Registration and Listing of Cosmetic Product Facilities and Products” and gave interested parties an opportunity to submit comments by September 7, 2023, for us to consider before beginning work on the final version of the guidance. We received numerous comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include additional information on the facility registration number, United States agent, electronic and paper submission, as well as incorporating FDA’s compliance policy we made available in a guidance for industry as described in the **Federal Register** of November 8, 2023 (88 FR 77323). In addition, we made editorial changes to improve clarity. New appendix B of this guidance is highlighted in grey, describes frequently asked questions and answers, and is marked “for comment purposes only” to provide an opportunity for comment before it is finalized. Aside from appendix B, this guidance finalizes the draft guidance that was published on August 8, 2023.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in section 607 of the FD&C Act have been approved under 0910–0599.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/CosmeticGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 12, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–27649 Filed 12–18–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–P–4596]

#### Determination That MEPHYTON (Phytonadione) Tablets, 5 Milligrams, Were 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 MEPHYTON (phytonadione) tablets, 5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5236, Silver Spring, MD 20993–0002, 301–796–8363, [Stacy.Kane@fda.hhs.gov](mailto:Stacy.Kane@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a

previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

MEPHYTON (phytonadione) tablets, 5 mg, are the subject of NDA 010104, held by Bausch Health Americas, Inc., and initially approved in 1955. MEPHYTON is a vitamin K replacement indicated for the treatment of adults with the following coagulation disorders, which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity:

- Anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives
- Hypoprothrombinemia secondary to antibacterial therapy
- Hypoprothrombinemia secondary to factors limiting absorption or synthesis of vitamin K, e.g., obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas, and regional enteritis
- Other drug-induced hypoprothrombinemia where it is

definitively shown that the result is due to interference with vitamin K metabolism, *e.g.*, salicylates

MEPHYTON (phytonadione) tablets, 5 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lachman Consults submitted a citizen petition dated October 17, 2023 (Docket No. FDA–2023–P–4596), under 21 CFR 10.30, requesting that the Agency determine whether MEPHYTON (phytonadione) tablets, 5 mg, were 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 MEPHYTON (phytonadione) tablets, 5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEPHYTON (phytonadione) tablets, 5 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MEPHYTON (phytonadione) tablets, 5 mg, 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 MEPHYTON (phytonadione) tablets, 5 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, 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: December 14, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–27858 Filed 12–18–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–4395]

#### Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.” FDA is issuing this draft guidance to clarify how FDA evaluates real-world data (RWD) to determine whether they are of sufficient quality for generating real-world evidence (RWE) that can be used in FDA regulatory decision-making for medical devices. This draft guidance proposes expanded recommendations to the 2017 guidance entitled “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.” This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 20, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *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–2023–D–4395 for “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.” Received comments 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