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under 21 CFR 10.30, requesting that the Agency determine whether MEPHYTON (phytonadione) tablets, 5 mg, were withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that MEPHYTON (phytonadione) tablets, 5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEPHYTON (phytonadione) tablets, 5 mg, were withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4164–01–P

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Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff; Availability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

the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 318, Silver Spring, MD 20993–0002, 301–796–6359; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to clarify how FDA evaluates RWD to determine whether they are of sufficient quality for generating 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'' (the 2017 RWE Guidance). On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 (FDORA) was signed into law as part of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). Section 3629 of FDORA ''Facilitating the Use of Real World Evidence'' directs FDA to issue or revise existing guidance on considerations for the use of RWD and RWE to support regulatory decision making. FDA is issuing this draft guidance to propose revisions to the 2017 RWE Guidance to satisfy the requirement under section 3629(a)(2). This draft guidance also fulfills a commitment in section V.F. of the Medical Device User Fee Amendments Performance Goals and Procedures, Fiscal Years 2023 Through 2027 (MDUFA V).

This draft guidance includes FDA's recommendations and considerations on the factors that are expected to be assessed to demonstrate whether the RWD are fit-for-purpose for a particular regulatory decision relating to medical devices. When this draft guidance is finalized, these recommendations and considerations will apply regardless of the RWD source and will encompass processes for conducting studies to generate RWE. A fit-for-purpose assessment should evaluate both the relevance and reliability of a RWD source, as discussed in more detail in the draft guidance. FDA recognizes that there may be other approaches to address the considerations identified in this draft guidance. We encourage sponsors to discuss their approach with FDA, especially if the approach diverges from the recommendations in this draft guidance, when finalized.

The topics covered within this draft guidance are framed specifically for the use of RWD/RWE in regulatory submissions. This draft guidance includes additional clarity regarding the recommended methodologies for collection and analysis of RWD to generate RWE, and provides updated examples on previously used and accepted methodologies. This draft guidance also provides additional clarity regarding the use of clinical data collected from the use of a device authorized under an Emergency Use Authorization (EUA) and to describe the type of information that could be applicable to support a determination under the Clinical Laboratory Improvement Amendments (CLIA) (*e.g.,* Waiver by Application).

FDA recognizes and anticipates that the Agency and industry may need up to 60 days to perform activities to operationalize the recommendations within the final guidance. At this time, the Agency anticipates that, for regulatory submissions that will be currently pending with FDA after publication of the final guidance, as well as those submissions received within 60 days following publication of the final guidance, FDA generally would not anticipate that sponsors will be ready to include the newly recommended information outlined in the final guidance in their submission. FDA, however, would intend to review any such information if submitted at any time.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.'' It does not 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.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00500012 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
822	Postmarket Surveillance of Medical Devices	0910–0449
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130
601	Biologics License Application	0910–0338
803	Medical Device Reporting	0910–0437
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
800, 801, 809, and 830	Medical Device Labeling Requirements; Unique Device Identification.	0910–0485
860	Reclassification Petition for Medical Devices	0910–0138
''Emergency Use Authorization of Medical Products and Related Authorities''.	EUA	0910–0595

Dated: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27852 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–N–2058]

James Funaro: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring James Funaro for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Funaro was convicted of one felony count under Federal law for conspiracy to launder money. The factual basis supporting Mr. Funaro's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Funaro was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of October 11, 2023 (30 days after receipt of the notice), Mr. Funaro had not responded. Mr. Funaro's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable December 19, 2023.

ADDRESSES: Any application by Mr. Funaro for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov*.
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–2058. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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 the information at: *https:/*