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–2022–N–3299 for ''Understanding the Use of Negative Controls to Assess the Validity of Non-Interventional Studies of Treatment Using Real-World Evidence.'' Received comments, those filed in a timely manner, 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. 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.

FOR FURTHER INFORMATION CONTACT: Jamila Mwidau, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 4481, Silver Spring, MD 20993, 301–796–4989, *Jamila.Mwidau@fda.hhs.gov;* or Stephen Ripley, 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

In connection with the seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA has committed to enhancing and modernizing the FDA drug safety system, including improving the utility of existing tools and adopting new scientific approaches. This commitment includes optimizing the capabilities of the Sentinel Initiative to address questions of product safety and advance the understanding of how Real-World Evidence can be used for studying effectiveness.

Under PDUFA VII, FDA agreed to conduct a public workshop by September 30, 2023, on the use of negative controls for assessing the validity of non-interventional studies of treatment. This public workshop, scheduled for March 8, 2023, will satisfy the PDUFA VII commitment. One purpose of the public workshop is to discuss current negative control methods in studies based on real-world data and discuss future implications for their use to evaluate the safety of regulated medical products. Another purpose of the public workshop is to present the proposed methods development projects that may support a tool for use in the Sentinel System and BEST.

II. Topics for Discussion at the Public Workshop

Some topics FDA plans to discuss at the public workshop include but may not be limited to the following:

1. What are the strengths and limitations of current negative control methods used in studies based on real-world data?

2. What are known and potential benefits and challenges in using negative controls in evaluating regulated product safety and effectiveness?

3. What additional information is needed about negative control methods to provide confidence regarding their use in regulatory decision-making?

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website to register: *https://duke.is/cy9w4.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and open until the public workshop is completed. Persons interested in attending this public workshop can register until 2:59 p.m. Eastern Standard Time on March 8, 2023.

If you need special accommodations due to a disability, please contact *margolisevents@duke.edu* no later than February 22, 2023.

Dated: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00840 Filed 1–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1982]

Determination That OFIRMEV (Acetaminophen) Injection, 1,000 Milligrams/100 Milliliters (10 Milligrams/Milliliter), 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, Agency, or we)

has determined that OFIRMEV (acetaminophen) injection, 1,000 milligrams (mg)/100 milliliters (mL) (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acetaminophen injection, 1,000 mg/100 mL (10 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–1546, *Kaetochi.Okemgbo@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.

OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), is the subject of NDA 022450, held by Mallinckrodt Hospital Products IP Ltd. (Mallinckrodt), and initially approved on November 2, 2010. OFIRMEV is indicated for management of mild to moderate pain in adult and pediatric patients 2 years and older, management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older, and reduction of fever in adult and pediatric patients.

In a letter dated June 24, 2021, Mallinckrodt notified FDA that OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Nines Consult Pharma, LLC, submitted a citizen petition dated August 22, 2022 (Docket No. FDA–2022–P–1982), under 21 CFR 10.30, requesting that the Agency determine whether OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), 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 OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), 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. ANDAs that refer to OFIRMEV (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL), may 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: January 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00792 Filed 1–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1600]

Gabriel J. Letizia, Jr.: 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) permanently debarring Gabriel J. Letizia, Jr. from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Letizia was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Letizia was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Letizia has not responded to the notice. Mr. Letizia's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable January 18, 2023.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires