has determined that OFIRMEV (acetaminophen) injection, 1,000 milligrams (mg)/100 milliliters (mL) (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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

debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On May 18, 2022, Mr. Letizia was convicted in the U.S. District Court for the Southern District of New York, of one felony count of conspiracy to commit wire fraud in violation of 18 U.S.C. 371, and two misdemeanor counts of misbranding in violation of 21 U.S.C. 331(a) and 333(a)(1). FDA's finding that debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the Superseding Information in Mr. Letizia's case, filed May 4, 2021, and from the transcript of his guilty plea hearing, filed on May 26, 2021, Mr. Letizia was the owner and executive director of AMA Laboratories (AMA), a consumer product testing company in Rockland County, New York. Mr. Letizia began operating AMA in the early 1980s and became its sole owner in approximately 2003. Mr. Letizia falsely used the title ''Dr.'' in correspondence, falsely representing to customers that he held a Ph.D. AMA purported to test the safety and efficacy of cosmetics, sunscreens, and other products on specified numbers of volunteer panelists for consumer products companies. AMA's customers would use the test results to support their claims that their products were safe, effective, hypoallergenic, or provided a certain sun protection factor (SPF), including after exposure to water. AMA customers that manufactured sunscreens used the test results to comply with FDA regulations requiring sunscreen manufacturers to have their products tested and to maintain the test results for possible review by the FDA.

From 1987 to April 2017, Mr. Letizia and AMA personnel operating at Mr. Letizia's direction, defrauded AMA's customers of more than $46 million by testing products on materially lower numbers of panelists than the numbers specified and paid for by AMA's customers. At Mr. Letizia's direction, AMA personnel rarely tested products on the number of panelists requested by AMA's customers and for which they had paid. AMA's fees for tests were based, in part, on the number of panelists that were to participate in the study. However, at Mr. Letizia's direction AMA sent its customers fraudulent test results, via interstate email and facsimile communications, in which AMA personnel included fictitious data for ''phantom'' panelists who had not actually participated in the tests. At Mr. Letizia's direction, AMA employees had panelists who agreed to partake in studies at AMA fill out consent forms and other paperwork as if they would be participating in all of the studies that were being performed at AMA at that time. These panelists were then used as ''phantom'' panelists in other studies, and their consent forms for those studies would falsely make it appear to those who might audit AMA's files, including FDA investigators and AMA's customers, that the panelists had participated in studies when, in fact, they had not. In addition, AMA customers who paid for AMA to test their sunscreen products relied on the reliability of AMA's test results for purposes of accurately and lawfully labeling the SPF level of the sunscreen products those customers intended to sell. Mr. Letizia knowingly caused AMA employees to send false reports to AMA's customers in that testing had not been performed on the whole panel as requested and paid for by AMA's customers. In so doing, Mr. Letizia knowingly caused AMA's customers to market and sell to consumers in the United States and elsewhere, sunscreen, with labels that failed to reveal material facts in that the labels on these products stated that the SPF level of the sunscreen was 50 with no indication on that label that the laboratory testing of the panel paid for by AMA customers had not been performed.

In addition, at Mr. Letizia's direction, AMA personnel routinely falsified test results relating to AMA's customers' products, which included suppressing reports of adverse reactions and deviating from testing protocols. AMA personnel reported adverse reactions to customers only in extreme cases and often offered to retest the product and, in some cases, change the test procedure with the hope of reducing the number of reported negative reactions. AMA personnel also falsified data to accord with prior results from smaller ''screener'' study results or customer expectations.

Based on this conviction, FDA sent Mr. Letizia by certified mail on September 12, 2022, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Letizia was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Letizia an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Letizia received the proposal on September 16, 2022. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Letizia has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Letizia is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Letizia during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Letizia provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Letizia during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Letizia for special termination of debarment under section 306(d)(4) of the FD&C Act) should be identified with Docket No. FDA–2022–N–1600 and sent to the Dockets Management Staff (see

ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: January 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00791 Filed 1–17–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3071]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on March 28 and 29, 2023, from 10 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–3071. Please note that late, untimely filed comments will not be considered. The docket will close on March 27, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 27, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before March 14, 2023, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2022–N–3071 for ''Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' FDA 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 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 the 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: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417,