inform public comment: (1) The draft clinical practice guideline; (2) the GRADE tables; (3) the Opioid Workgroup (OWG) Report, prepared at the request of the BSC/NCIPC and which the BSC/NCIPC unanimously voted to have CDC adopt, and CDC's response to observations outlined in the OWG Report; and (4) an Overview of Community Engagement and Public Comment Opportunities, which describes key themes that emerged about stakeholders' values and preferences regarding pain management, as well as CDC's response to input obtained from these efforts. The GRADE tables include clinical evidence review ratings of the evidence for the key clinical questions. The OWG Report describes the workgroup's findings and observations about the initial draft clinical practice guideline as presented to the BSC/NCIPC at a public meeting on July 16, 2021. The OWG, comprising three BSC/NCIPC members in accordance with federal advisory committee policy, as well as patients with pain, caregivers, and family members of patients with pain, and clinicians and subject matter experts with a variety of relevant pain management expertise, was designed to provide independent, broad, external, transparent input to the BSC/NCIPC on the diverse and complex issues addressed in the clinical practice guideline. OWG meetings were coordinated by an NCIPC subject matter expert who served as the Designated Federal Official. CDC's response to the OWG Report reflects and describes how CDC incorporated OWG observations and comments in the revised draft of the clinical practice guideline. The *Overview of Community Engagement and Public Comment Opportunities* document provides a summary of efforts implemented throughout the clinical practice guideline update process to better understand the lived experiences and perspectives of community members that we serve and to ensure additional input from patients, caregivers, clinicians, and the public. CDC's response to the themes and findings that emerged throughout the community engagement and public comment opportunities describes how CDC carefully considered and incorporated diverse perspectives and input from multiple sources and stakeholders into the clinical practice guideline.

Dated: February 7, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–02802 Filed 2–9–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1030]

Brenda K. Marmas: 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 Brenda K. Marmas 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 Ms. Marmas engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Ms. Marmas was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 12, 2021 (30 days after receipt of the notice), Ms. Marmas had not responded. Ms. Marmas' failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable February 10, 2022.

ADDRESSES: Submit applications for 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 Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240 402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer), and the shipments are not designated in an entry in an authorized electronic data exchange system as products regulated by FDA.

After an investigation, FDA discovered that Ms. Marmas has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the John F. Kennedy International Airport (JFK), San Francisco International Airport (SFO), or Chicago International Airport Mail Facilities (MF) and were addressed to Ms. Marmas at an address connected to her.

On or about March 3, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 tablets of levofloxacin IP and was a misbranded drug for a number of reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act (21 U.S.C. 360(j)); and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. FDA also determined that another product contained in this parcel was 900 tablets of moxifloxacin hydrochloride and was a misbranded drug for a number of reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. Both products were refused entry on March 26, 2020.

On or about March 3, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of azithromycin IP and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA also determined that one of the products contained in this parcel was 600 tablets of azithromycin IP and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on March 25, 2020.

On or about July 8, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,304 capsules of azithromycin 250 milligrams (mg) and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 5, 2020.

On or about July 17, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of amoxicillin 875 mg and was a misbranded drug for multiple reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 1,400 capsules of clindamycin 300 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and the drug was not included in a list required by section 510(j) of the FD&C Act. Both products were refused entry on September 23, 2020.

On or about July 17, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 84 tablets of azithromycin 250 mg and was a misbranded drug for multiple reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 1,800 capsules of clindamycin 150 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 500 tablets of roxithromycin 150 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. All three products were refused entry on September 23, 2020.

On or about July 21, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,520 capsules of fluconazole 200 mg and was a misbranded drug because the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act and because the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 17, 2020.

On or about July 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,000 capsules of doxycycline hyclate 100 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only.'' The product was refused entry on October 5, 2020.

On or about July 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 500 capsules of amoxicillin trihydrate 500 mg and was a misbranded drug for multiple reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that one of the other products contained in this parcel was 2,000 capsules of clindamycin 300 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that one of the other products contained in this parcel was 300 tablets of amoxicillin/clavulanic acid 875 mg/125 mg and was a misbranded drug for multiple reasons: (1) The article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. All three products were refused entry on October 9, 2020.

On or about July 31, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 576 capsules of azithromycin 250 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and the article had been determined to lack adequate directions for use. FDA determined that the other product contained in this parcel was 1,600 tablets of clarithromycin 500 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on September 4, 2020.

On or about August 13, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,860 capsules of doxycycline hyclate 100 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only.'' The product was refused entry on October 6, 2020.

On or about September 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. FDA determined that the product contained in this parcel was 1,000 tablets of amoxycillin and potassium clavulanate IP and was a misbranded drug because the drug was manufactured, prepared, propagated,

compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act and because the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on October 26, 2020.

On or about October 2, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 230 tablets of LQUIN levofloxacin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and the article had been determined to lack adequate directions for use. FDA determined that the other product contained in this parcel was 129 tablets of AZICIP azithromycin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label and the article had been determined to lack adequate directions for use. Both products were refused entry on October 28, 2020.

On or about October 16, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,500 capsules of amoxicillin and was a misbranded drug for multiple reasons: (1) The required label or labeling was determined to not be in English in violation of § 201.15(c)(1) (21 CFR 201.15(c)(1)); (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act; and (5) the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that the other product contained in this parcel was 1,600 tablets of FLOXCIPRO 250 ciprofloxacin and was a misbranded drug for multiple reasons: (1) The required label or labeling was determined to not be in English in violation of § 201.15(c)(1); (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act; and (5) the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on December 3, 2020.

On or about November 16, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of AZICIP azithromycin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that the other product contained in this parcel was 1,000 tablets of CIPRODAC ciprofloxacin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on December 10, 2020.

On or about December 15, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 capsules of cephalexin IP 500 mg (CEPHADEX 500) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that one of the products contained in this parcel was 30 capsules of vancomycin hydrochloride IP 250 mg (VANLID 250) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that one of the other products contained in this parcel was 250 tablets of trimethoprim and sulphamethoxazole IP (BACTRIM DS) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. All three products were refused entry on January 19, 2021.

On or about April 23, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 capsules of RESTECLIN 500 (tetracycline) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. FDA determined that one of the products contained in this parcel was 400 tablets of RIFAGUR 400 (rifaximin) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. Both products were refused entry on May 18, 2021.

On or about May 26, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 500 tablets of amoxycillin and potassium clavulanate IP and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on June 25, 2021. FDA determined that the other product contained in this parcel was 300 tablets of azithromycin IP 500 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. This product was refused entry on June 24, 2021.

On or about July 15, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. FDA determined that the product contained in this parcel was 500 tablets of amoxycillin and potassium clavulanate IP; CIPMOX CV–625 and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 13, 2021.

As a result of this pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Ms. Marmas, by certified mail on November 3, 2021, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Marmas' pattern of conduct and concluded that her conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Marmas of the proposed debarment and offered her

an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Marmas received the proposal and notice of opportunity for a hearing on November 12, 2021. Ms. Marmas failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment. (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Brenda K. Marmas has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Marmas is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Ms. Marmas is a prohibited act.

Any application by Ms. Marmas for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–1030 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

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

Dated: February 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02801 Filed 2–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0556]

Development of Non-Opioid Analgesics for Acute Pain; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Development of Non-Opioid Analgesics for Acute Pain.'' In connection with the SUPPORT for Patients and Communities Act (SUPPORT Act), the purpose of this guidance is to spur the development of alternatives to opioids for the management of acute pain by providing information about product development-related issues, ''opioid-sparing'' claims, and expedited programs as they pertain to this purpose.

DATES: Submit either electronic or written comments on the draft guidance by April 11, 2022 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–2021–N–0556 for ''Development of Non-Opioid Analgesics for Acute Pain.'' 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