explains that, prior to November 27, 2023, FDA does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D) of the FD&C Act. The guidance explains the scope of the compliance policy in further detail.

By extending the delay in enforcement initially provided in the 2019 Compliance Policy until November 27, 2023, FDA believes that wholesale distributors will be able to focus resources and efforts on the requirements for the enhanced drug distribution security system, provided for in section 582(g) of the FD&C Act and required by November 27, 2023. Instead of developing separate processes or infrastructures solely for the saleable return verification requirement, wholesale distributors can incorporate the saleable return verification requirements into enhanced verification required by 2023. Given this consideration, FDA has not adopted the approach suggested by some comments suggesting that the Agency revise the 2019 Compliance Policy to provide for a phased implementation of the saleable return verification requirements.

FDA also received comments requesting that we extend the scope of the 2019 Compliance Policy beyond wholesale distributors to also cover manufacturers and repackagers, asking FDA to not take enforcement action where manufacturers and repackagers are not in compliance with their verification of saleable returned product obligations under section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act. At this time, we do not intend to broaden the scope of the 2019 Compliance Policy in this way because we believe the policies outlined in this guidance will provide appropriate flexibility. As all trading partners work towards enhanced system requirements that go into effect in 2023, wholesale distributors can continue to work with manufacturers and repackagers for enhanced verification requirements, including those for saleable returned product. FDA intends to issue additional guidance about the enhanced system for drug distribution security at a later date.

Finally, section 582 of the FD&C Act, as amended by the DSCSA, also established the requirements that specify how dispensers must investigate suspect and illegitimate product. As part of the investigation, section 582(d)(4)(A)(ii)(II) of the FD&C Act requires dispensers to verify the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product in the dispenser's possession or control, beginning November 27, 2020. Section 582(d)(4)(B)(iii) of the FD&C Act requires dispensers to verify product as described in section 582(d)(4)(A)(ii), which includes the section 582(d)(4)(A)(ii)(II) requirement, in response to a notification of illegitimate product from FDA or a trading partner.

In response to comments received from stakeholders, this guidance also announces that FDA does not intend to take action before November 27, 2023, against dispensers who do not verify the statutorily-designated portion of product identifiers of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act, and that part of section 582(d)(4)(B)(iii) of the FD&C Act that requires dispensers to perform the same verification activities of section 582(d)(4)(A)(ii)(II) when responding to a notification of illegitimate product from FDA or another trading partner. FDA believes that dispensers can use the 3-year period to ensure the systems and processes that are put into place to meet the enhanced system requirements by November 27, 2023, will also fulfill all dispenser verification requirements under section 582(d)(4) of the FD&C Act.

This guidance represents the current thinking of FDA on ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' 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. Paperwork Reduction Act of 1995

FDA tentatively concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: October 19, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23524 Filed 10–22–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0862]

Captain Neill's Seafood, Inc.: Final Debarment Order

AGENCY: Food and Drug Administration

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 Capt. Neill's Seafood, Inc. (Capt. Neill's or the Company) for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Capt. Neill's was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. The Company was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of 30 days after receipt of the notice (July 13, 2020), Capt. Neill's has not responded. Capt. Neill's failure to respond and request a hearing constitutes a waiver of the Company's right to a hearing concerning this matter.

DATES: This order is effective October 23, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article

for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2020, Capt. Neill's was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the U.S. District Court for the Eastern District of North Carolina, when the court accepted the Company's plea of guilty and entered judgment against it for the offense of violating the Lacey Act and Aiding and Abetting. This offense was in violation of 16 U.S.C. 3372(d)(1), 3373(d)(3)(A)(i) and (ii), and 18 U.S.C. 2.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Indictment, filed on June 26, 2019, Capt. Neill's is a North Carolina corporation in the business of purchasing, processing, packaging, transporting, and selling seafood and seafood products, including crab meat from domestically harvested Atlantic blue crab, and products made from Atlantic blue crab. From as early as January 1, 2012 and continuing through December 31, 2015, Capt. Neill's purchased foreign crab meat from South American and Asia. Capt. Neill's employees repacked the foreign crab meat into containers labeled ''Product of USA.'' Capt. Neill's employees then knowingly sold those containers of foreign crab meat as jumbo domestically harvested blue crab to customers. During the relevant time frame, Capt. Neill's sold approximately 200,536 pounds of crab meat falsely labeled ''Product of USA'' with a total retail market value of $4,082,841.

As a result of this conviction FDA sent Capt. Neill's, by certified mail on May 6, 2020, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Capt. Neill's felony conviction of violating the Lacey Act and Aiding and Abetting in violation 16 U.S.C. 3372(d)(1), 3373(d)(3)(A)(i) and (ii), and 18 U.S.C 2, constitutes conduct relating to the importation into the United States of an article of food because the offense involved Capt. Neill's employees falsely labeling crabmeat that was imported from foreign countries and purporting that the crabmeat was a ''Product of USA.''

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Capt. Neill's should be subject to a 5-year period of debarment. The proposal also offered Capt. Neill's an opportunity to request a hearing, providing the Company 30 days from the date of receipt of the letter in which to file the request, and advised Capt. Neill's that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Capt. Neill's failed to respond within the timeframe prescribed by regulation and has, therefore, waived the Company's opportunity for a hearing and waived any contentions concerning Capt. Neill's debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Capt. Neill's has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that the Company is subject to a 5-year period of debarment.

As a result of the foregoing finding, Capt. Neill's is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (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 an article of food by, with the assistance of, or at the direction of Capt. Neill's Seafood, Inc. is a prohibited act.

Any application by Capt. Neill's for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–0862 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. 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 *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0861]

Phillip R. Carawan: 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 Phillip R. Carawan for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Carawan was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Carawan was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of June 13, 2020 (30 days after receipt of the notice), Mr. Carawan has not responded. Mr. Carawan's failure to respond and request a hearing constitutes a waiver of Mr. Carawan's right to a hearing concerning this matter.

DATES: This order is applicable October 23, 2020.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029) Division of Enforcement, 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)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.