this relate to Professionals Trained? This heading may belong to the last worksheet.

Services & Expenditures

Assuming that grantees can accurately report these totals if they have more granular data, there wouldn't be much more burden added if grantees reported the details behind ''Total Units of Direct Service Delivered.'' This should be broken out by service/expenditure type. Also, there should be separate column for PLWD and for CG. As noted previously, direct services for PLWD should be separated from direct services for the CG to get a better understanding the impact AD caregiving on family members.

The proposed data collection tools may be found on the ACL website for review at *https://nadrc.acl.gov/node/226*.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Local Program Site	180	2	3.03	1,090.8
Grantee	90	2	6.93	1,247.4
Total				2,338.2

Dated: October 15, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–23472 Filed 10–22–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4212]

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies; 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 final guidance for industry entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' This guidance explains that FDA intends to extend the delay in enforcement described in the guidance entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy,'' published in the **Federal Register** on September 24, 2019 (the 2019 Compliance Policy), which relates to Drug Supply Chain Security Act (DSCSA) provisions requiring wholesale distributors to verify the product identifier prior to further distributing returned product beginning on November 27, 2019. In addition, this guidance announces FDA's intended enforcement policy with respect to DSCSA provisions requiring dispensers to verify the product identifier for suspect or illegitimate product in the dispenser's possession or control beginning on November 27, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on October 23, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–4212 for ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' 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)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies.'' FDA does not intend to take action against wholesale distributors who do not, prior to November 27, 2023, verify the product identifier prior to further distributing returned product as required under the DSCSA (Title II of Pub. L. 113–54). This represents an additional 3-year delay from the delay set forth in the 2019 Compliance Policy in enforcement of the requirement for wholesale distributors to verify the product identifier prior to further distributing that returned product. In addition, FDA does not intend to take action against dispensers who do not verify the statutorily-designated portion of product identifiers of suspect or illegitimate product before November 27, 2023. This policy represents a 3-year delay in enforcement of the requirements for dispensers to verify the product identifier when investigating suspect or illegitimate product.

This guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). FDA made this determination because this guidance document provides information pertaining to statutory requirements that take effect November 27, 2020, for dispensers to verify the product identifier, including the standardized numerical identifier, for product in the dispenser's possession or control under section 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act (21 U.S.C. 360eee–1(d)(4)(A)(ii)(II) and (d)(4)(B)(iii)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)).

Beginning November 27, 2019, wholesale distributors were required, under section 582(c)(4)(D) (21 U.S.C. 360eee–1(c)(4)(D)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product, prior to further distributing such returned product. In the **Federal Register** published September 24, 2019 (84 FR 50044), FDA issued a notice announcing the availability of the 2019 Compliance Policy. The 2019 Compliance Policy indicated the Agency's intent to take no enforcement action against wholesale distributors who are not in compliance with this requirement under section 582(c)(4)(D) of the FD&C Act before November 27, 2020.

Since the announcement of the 2019 Compliance Policy, FDA has received additional comments and feedback from wholesale distributors, as well as other trading partners and stakeholders, expressing concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors and the challenges stakeholders face with developing interoperable, electronic systems to enable such verification and achieve interoperability between networks. Specifically, comments received point out continuing challenges posed by the large volume of saleable returned product, explaining that wholesale distributors still need more time to test verification systems using real-time volumes of saleable returned product with all trading partners involved, as opposed to using small-scale pilot test projects. Additionally, wholesale distributors point to significant delays in testing these verification systems due to the competing priority of responding to the Coronavirus Disease 2019 (COVID–19) pandemic, namely the reassignment of logistics and supply chain experts from DSCSA matters to COVID–19 pandemic response. Given all these concerns, FDA recognizes that some wholesale distributors may need additional time beyond November 27, 2020, before they can begin verifying returned products prior to resale or other further distribution as required by section 582(c)(4)(D) of the FD&C Act in an efficient, secure, and timely manner.

To minimize possible disruptions in the distribution of certain prescription drugs in the United States, FDA has adopted the compliance policy described in this guidance. Under this compliance policy, FDA does not intend to take action before November 27, 2023, against wholesale distributors who do not verify a product identifier prior to further distribution of a package or sealed homogenous case of product as required by section 582(c)(4)(D) of the FD&C Act.

Additionally, section 582 of the FD&C Act requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement when engaging in transactions involving certain prescription drugs. Section 581(27)(E) of the FD&C Act (21 U.S.C. 360eee(27)(E)) requires that the transaction statement include a statement that the entity transferring ownership in a transaction had systems and processes in place to comply with verification requirements under section 582 of the FD&C Act. This guidance also

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]

BILLING CODE 4164–01–P

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