*Authority:* Public Law 67–13, 42 Stat. 20 (June 10, 1921).

**James R. Dalkin,**

*Director, Financial Management and Assurance, U.S. Government Accountability Office.*

[FR Doc. 2023–02124 Filed 2–1–23; 8:45 am]

**BILLING CODE 1610–02–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2826]**

### Allergan Sales LLC., et. al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on November 21, 2022. The document announced the withdrawal of approval (as of December 21, 2022) of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDAs after receiving withdrawal requests from Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195: ANDA 076434, Chlorhexidine Gluconate Solution, 0.12%; Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180: ANDA 201832, Nimodipine Capsules, 30 milligrams (mg); and Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713: ANDA 203419, Donepezil HCl Tablets, 23 mg. Before FDA withdrew the approval of these ANDAs, Sunstar Americas, Inc., Sofgen Pharmaceuticals, LLC, and Indicus Pharma, LLC informed FDA that they did not want the approval of the ANDAs withdrawn. Because Sunstar Americas, Inc. timely requested that approval of ANDA 076434 not be withdrawn, Sofgen Pharmaceuticals, LLC timely requested that the approval of ANDA 201832 not be withdrawn, and Indicus Pharma, LLC timely requested that the approval of ANDA 203419 not be withdrawn, the approvals are still in effect.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Monday, November 21, 2022 (87 FR 223), in FR Doc. 2022–25315, the following correction is made:

On page 70835, in the table, the entries for ANDAs 076434, 201832, and 203419 are removed.

Dated: January 30, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–02155 Filed 2–1–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0086]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Potential Tobacco Product Violations Reporting Form.

**DATES:** Either electronic or written comments on the collection of information must be submitted by April 3, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 3, 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.

*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–2014–N–0086 for ''Potential Tobacco Product Violations Reporting Form.'' 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.'' 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.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Potential Tobacco Product Violations Reporting Form**

*OMB Control Number 0910–0716—Extension*

This information collection supports the opportunity to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA authority to monitor compliance with Federal tobacco laws and regulations and take corrective action when violations occur.

As part of its enforcement strategy, FDA accepts information from the public regarding potential tobacco product violations of the FD&C Act. Potential tobacco product violations include (but are not limited to): (1) sales to underage purchasers (persons under 21); (2) flavored cigarette sales; (3) illegal marketing and advertising; (4) distribution of free samples of tobacco products except in limited circumstances; (5) placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas); and (6) sale of cigarettes in packages of less than 20.

FDA currently provides a form that may be used to collect this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report). The Potential Tobacco Product Violations Report, Form FDA 3779, asks for the following information: (1) date potential violation occurred; (2) product type (*e.g.,* cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); (3) tobacco brand; (4) potential violation type; (5) type of potentially violative promotional materials; (6) who potentially violated; (7) name, address, phone number, and email address of the potential violator (if known); (8) potential violator's website or internet address URL (if available); (9) description of the potential violation; and (10) any additional files or information pertinent to the potential violation.

The public and interested stakeholders can report possible tobacco product violations of the FD&C Act by submitting information on Form FDA 3779 online, via email or postal mail, or by calling FDA's Tobacco Call Center. Information on how to submit possible tobacco product violations using the options above can be found at *https://www.accessdata.fda.gov/scripts/ptvr/index.cfm.* Further details about reporting possible tobacco product violations of the FD&C Act can also be found at *https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.*

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity and form FDA 3779 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Reporting potential tobacco product violations of the FD&C Act. | 3,000 | 2 | 6,000 | 0.25 (15 minutes) ..... | 1,500 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on the type and rate of reporting submitted through the Potential Tobacco Violation Report Form and based on a review of the information collection since our last

request for OMB approval. FDA estimates that submitting the information (online, telephone, email, or mail) will take 0.25 hours (*i.e.,* 15 minutes) per response.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,500 hours (6,000 responses × 0.25 hours per response).

Our estimated burden for the information collection reflects an overall increase of 157 hours and a corresponding increase of 630 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: January 30, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–02172 Filed 2–1–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–N–2109]**

### Sami Anwar; Denial of Hearing; Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is denying a request for a hearing submitted by Sami Anwar (Anwar) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Anwar from providing services in any capacity to a person having an approved or pending drug product application. FDA bases this order on a finding that Anwar was convicted of felonies under Federal law for conduct relating to the development or approval of any drug product or otherwise relating to the regulation of a drug product under the FD&C Act. Anwar failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

**DATES:** The order is applicable February 2, 2023.

**ADDRESSES:** Any application for special termination of debarment by Anwar under section 306(d) of the FD&C Act (application) may be submitted as follows:

*Electronic Submissions*

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* Your application must include the Docket No. FDA–2020–N–2109. An application will be placed in the docket and, unless 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)) mandates permanent debarment if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act.

On October 1, 2020, the U.S. District Court for the Eastern District of Washington entered a judgment against Anwar, after a jury verdict, for 24 counts of wire fraud in violation of 18 U.S.C. 1349, 15 counts of mail fraud in violation of 18 U.S.C. 1341, 1 count of conspiracy to commit mail fraud in violation of 18 U.S.C. 371, 6 counts of fraudulently obtaining controlled substances in violation of 21 U.S.C. 843(a)(3), and 1 count of furnishing false or fraudulent material information to