the Drug Enforcement Administration in violation of 21 U.S.C. 843(a)(4)(A). As described below, the basis of Anwar's convictions stems from Anwar and his companies' falsifying research data for human clinical trials, including forging and falsifying documents to make it appear as though such clinical trials were performed and supervised by a qualified and licensed physician and falsifying medical records and data to admit dozens of ineligible subjects into the clinical trials.

By letter dated January 6, 2021, FDA's Office of Regulatory Affairs (ORA) notified Anwar of a proposal to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application and provided him an opportunity to request a hearing. As explained in the notice, the basis for the proposed debarment is Anwar's felony convictions in the U.S. District Court for the Eastern District of Washington. According to ORA, Anwar is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he 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.

The proposal to debar states that the convictions relate to Anwar's role as owner and operator of Mid-Columbia Research LLC and Zain Research LLC, contract research organizations that oversaw and conducted clinical research trials on a contract basis for various drug sponsors. As described in the proposal, Anwar directed and carried out a conspiracy to have his companies fraudulently pose as legitimate human clinical research trial sites, and Anwar provided false clinical research trial data regarding drug safety and drug efficacy to dozens of drug companies and, through them, FDA, which regulates human clinical trials in the United States. Anwar also posed as a doctor and forged the signatures of the doctors he employed. In addition, Anwar directed his employees to assist in committing the fraud, including: (1) falsifying medical records and data to admit dozens of ineligible research subjects, (2) falsifying research data vital signs, (3) stealing blood samples taken from patients without their knowledge or consent, (4) directing patients to dispose of study medications and then falsely record dispensing as required by the study, (5) fraudulently obtaining and acquiring opioids intended to be dispensed to study subjects, and (6) falsifying subject diaries. In the proposal to debar, ORA found that Anwar's convictions, and underlying conduct, relate to the process for development or approval, including the process for development or approval, of any drug product and for conduct relating to the regulation of any drug product under the FD&C Act.

In a letter dated January 22, 2021, Anwar submitted a ''request for an extension of the hearing.'' This letter did not contain a request for a hearing, but the Director of the Office of Scientific Integrity, who has the authority to rule upon debarment matters, construed it as one. In addition, Anwar was given an extension to submit any information or factual analyses in support of his request for a hearing until April 15, 2021. Anwar has not filed any additional information to support his request.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Anwar's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

Since Anwar has not presented any information to support his hearing request, the Chief Scientist concludes that Anwar failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, the Chief Scientist denies Anwar's request for a hearing.

II. Findings and Order

The Chief Scientist, under section 306(a)(2) of the FD&C Act and under the authority delegated to her, finds that Sami Anwar has been convicted of felonies 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 a drug product under the FD&C Act.

As a result of the foregoing findings, Sami Anwar is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Anwar, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Anwar, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Anwar during his period of debarment.

Dated: January 27, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023–02161 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–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; 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 the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on FDA's website entitled ''Postmarketing Requirements and Commitments: Reports'' (*https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Diane Maloney, Center for Biologics

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7242, Silver Spring, MD 20993–0002, 240–402–8113.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants are required to, or have committed to, conduct and for which annual status reports have been submitted. Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drug products and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application, as applicable. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertakento investigate a safety issue . . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2021 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year (FY) 2021 (*i.e.,* as of September 30, 2021). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) the number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year (FY) of establishment [2] (FY2015 to FY2021) for PMRs and PMCs open at the end of FY2021, or those closed within FY2021. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.*

Dated: January 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02156 Filed 2–1–23; 8:45 am]

BILLING CODE 4164–01–P

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0386–Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Delta States Rural Development Network Grant Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than April 3, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386–Extension.

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)). The Delta Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of Delta Program-supported projects are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability. HRSA collects information from Delta Program award recipients using an OMB-approved set of performance measures and seeks to extend that approved information collection.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to HRSA including the following: (a) access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. These measures