calculating discrepancy rates since it cannot be generalizable for all reporting clinics.

Since information on potential data errors is not available from non-validated clinics and CDC's annual data validation only represents a very small proportion of clinics (7–10%) and cycles (1% of total reported cycles), correcting identified discrepancies in the final dataset for a small subset of cycles will not have any significant effect on data quality or published success rates. However, CDC took into account comments that publishing inaccurate data with known *major* discrepancies can be misleading, even in the presence of a footnote describing data quality concerns. Therefore, if a clinic is selected to participate in the NASS data validation process (either through stratified random sampling or through targeted selection), does participate, and major data discrepancies are identified (*e.g.,* lack of supporting information for a significant proportion of reported pregnancy outcomes, inability to confirm a significant proportion of reported live births, underreporting a significant proportion of cycles, etc.), a message will be displayed in the ART Fertility Clinic Success Rates Report for the clinic as:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was visited for validation of (insert: reporting year) data and major data discrepancies were identified. This clinic's reported success rates data are therefore not published in this report and not included in aggregate national data reports.

CDC may re-select this ART program for data validation during the following reporting year(s) to assess corrections of identified data errors.

In addition, CDC will publish information in the annual ART Fertility Clinic Success Rates Report to identify clinics that are selected by CDC to participate in the NASS data validation but decline to participate. (See 80 FR 51811 for further information concerning external validation of clinic data). If a clinic is selected to participate in the NASS data validation process and declines to participate, the following message will be displayed in the ART Fertility Clinic Success Rates Report for the clinic as:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was selected for validation of (insert: reporting year) data, but declined to participate. This clinic's reported data are therefore not published in this report and not included in aggregate national data reports.

CDC may re-select this ART program for data validation during the following reporting year(s). Participation in data validation is integral to helping ensure the accuracy of the required pregnancy success rates reported to have been achieved by clinics. Therefore, displaying this message, as well as the other messages outlined herein, is important in providing the public with the most accurate information.

For consistency, for all other clinics that are selected to participate in the NASS data validation and do participate, the following footnote will be added:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was visited for validation of (insert: reporting year) data and no systematic problems were identified.

Any messages added to a clinic's success rates page in the ART Fertility Clinic Success Rates Report will appear only for the reporting year that the clinic was selected for validation. These enhanced processes and messages in the annual ART Fertility Clinic Success Rates Report will help to inform the public if there are issues with data quality, thereby increasing the transparency and help ensure the accuracy of the NASS data reporting.

For 2017 reporting year, CDC started reporting cumulative success rates which take into account successes over all embryo transfers within 12-month period from a single oocyte retrieval and, therefore, span two reporting years (83 FR 53253). Effective for data validation conducted in calendar year 2021, data validation approach will be aligned with ART reporting approach and will also span two reporting years. Data validation conducted in 2021 will cover oocyte retrievals conducted in reporting year 2018 and associated embryo transfers that took place within 12-month period from oocyte retrievals (reporting years 2018 and 2019). As a result of this transition to a cumulative approach in data validation and due to impacts of the COVID–19 pandemic (*i.e.,* travel restrictions), no data validations will be conducted in calendar year 2020.

Dated: October 15, 2020.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2020–23188 Filed 10–19–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Identifying and Addressing Human Trafficking in Child Welfare Agencies (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS) is proposing to collect data on child welfare agencies' efforts to identify human trafficking and subsequent service delivery. The goal of the study is to better understand child welfare practice in screening for human trafficking, and the degree to which screening is related to subsequent referrals for, access to, and delivery of specialized services for children identified as trafficking victims or at high risk of trafficking.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: ACF is proposing data collection as part of the study, ''Identifying and Addressing Human Trafficking in Child Welfare Agencies,'' exploring child welfare practice in screening for human trafficking, and the relationship between screening and specialized services.

Primary data collection includes semi-structured qualitative interviews

with state and local human trafficking coordinators (or comparable staff members with greatest knowledge about human trafficking efforts); small group interviews with casework supervisors; and case narrative interviews with caseworkers.

The interviews will be conducted by telephone (25 state agencies) and in-person (up to 8 local agencies or offices). Interview questions will be focused on how agencies select, train on, and implement screening for human trafficking, the details of screening protocols, and variations in implementation. Questions will also address the availability of specialized services for children identified as trafficking victims or at high risk of trafficking, agency steps based on positive or suspected screening, and the process for initiating specialized services.

Respondents: State and local human trafficking coordinators, casework supervisors, and caseworkers.

Annual Burden Estimates

Data collection is expected to take place over two years.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
State Human Trafficking Coordinator Telephone Interview Guide	25	1	1.5	37.5	19
Local Human Trafficking Coordinator Interview Guide	8	1	1.5	12	6
Casework Supervisor Group Interview Guide	40	1	1.5	60	30
Caseworker Case Narrative Interview Guide	48	1	1	48	24

Estimated Total Annual Burden Hours: 79.

Authority: Section 476(a)(1–2) (42 U.S.C. 676) of the Social Security Act Part E—Federal Payments for Foster Care and Adoption Assistance.

John M. Sweet Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–23160 Filed 10–19–20; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1058]

Keith Komar: 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 Keith Komar 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 Mr. Komar was convicted of one felony count under Federal law for mail fraud. The factual basis supporting Mr. Komar's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Komar was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of 30 days after receipt of the notice (July 22, 2020), Mr. Komar had not responded. Mr. Komar's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable October 20, 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.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, 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)(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)(C) 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 drug or controlled substance. On November 7, 2019, Mr. Komar was convicted, as defined in section 306(*l*)(1) of the FD&C Act, in the U.S. District Court for the Western District of Pennsylvania, when the court entered judgment against him for the felony offense of mail fraud in violation of 18 U.S.C. 1341.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in count 3 of the indictment in Mr. Komar's case, filed on November 29, 2017, to which Mr. Komar pleaded guilty, on or about December 7, 2015, Mr. Komar, for the purpose of executing a scheme and artifice to defraud, and in attempting to do so, knowingly caused the U.S. mail to deliver from Mumbai, India, a parcel containing misbranded drugs. Specifically, the parcel contained 30 tablets of the unapproved new prescription drug bicalutamide and 30 gelcaps of the unapproved new prescription drug isotretinoin. These drugs were misbranded because, as contained in the indictment in Mr. Komar's case, they were dispensed to consumers without a valid prescription from a practitioner licensed by law to administer such drugs, and they did not contain labeling bearing adequate directions for use. As detailed in facts contained in counts 1, 2, and 4 of Mr. Komar's indictment (facts which Mr. Komar acknowledged responsibility for in his plea agreement), Mr. Komar was part of a criminal conspiracy. As part of this criminal conspiracy, Mr. Komar's intent was to fraudulently import this misbranded bicalutamide and isotretinoin and sell them in interstate commerce to customers of Mr. Komar's websites. On these websites Mr. Komar made a number of false statements to potential customers, such as that he provided ''high quality, safe, and approved medications meeting or exceeding the U.S. FDA standard.'' In addition, Mr. Komar later did in fact cause the introduction and delivery for introduction of misbranded drugs (bicalutamide and isotretinoin) into interstate commerce with the intent to defraud and mislead by selling these unapproved new prescription drugs to a