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

customer who did not have a prescription for them. A member of the conspiracy caused the customs declaration on the parcel to falsely report that the parcel contained a health product sample with no declared value.

As a result of this conviction, FDA sent Mr. Komar, by certified mail on June 11, 2020, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Komar's felony conviction for one felony count under Federal law for mail fraud was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally caused bicalutamide and isotretinoin to be introduced in interstate commerce from Mumbai, India, by selling to a consumer who did not have a prescription through the U.S. mail in violation of 18 U.S.C. 1341.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Komar's offenses and concluded that this felony offense warranted the imposition of a 5-year period of debarment. The proposal informed Mr. Komar of the proposed debarment and offered Mr. Komar an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Komar received the proposal and notice of opportunity for a hearing on June 22, 2020. Mr. Komar failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Keith Komar has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Komar is debarred for a period of 5 years from importing or offering for import any drug 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 any drug or controlled substance by, with the assistance of, or at the direction of Mr. Komar is a prohibited act.

Any application by Mr. Komar for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–1058 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23135 Filed 10–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Maternal Health Portfolio Evaluation Design, OMB No. 0906–xxxx–NEW

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 19, 2020.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal Health Portfolio Evaluation Design, OMB No. 0906–xxxx [NEW].

Abstract: HRSA programs provide health care to people who are geographically isolated, economically, or medically vulnerable. HRSA programs help those in need of high quality primary health care, such as pregnant women and mothers. Improving maternal health outcomes and access to quality maternity care services is a key component of the HRSA mission. HRSA's Maternal and Child Health Bureau (MCHB) provides funding to address some of the most urgent issues influencing the high rates of maternal mortality. Recent efforts to address persistent disparities in maternal, infant, and child health have employed a ''life course'' perspective and health equity lens focused on health promotion and disease prevention. Life course approach can be defined as analyzing people's lives within structural, social, and cultural contexts through a defined sequence of age categories that people are normally expected to pass through as they progress from birth to death. Health equity is defined as the attainment of the highest level of health for all people.

Achieving health equity for pregnant and postpartum women will require attention to barriers in access to quality health services and promotion of equal opportunities to seek the highest possible level of health and well-being. Achieving health equity also requires a focus on social determinants of health.

With this emphasis on improving maternal health across the life course and promoting optimal health for all mothers, HRSA is employing a multipronged strategy to address maternal mortality and severe maternal morbidity through the following suite of programs:

1. The State Maternal Health Innovation Program;