DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Information Collection for HHS Certification of Foreign Adult Victims of Human Trafficking.

OMB No.: 0970–0454.

Description: The Trafficking Victims Protection Act, Public Law 106–386 (TVPA) requires the Department of Health and Human Services (HHS) to certify adult alien ("foreign") victims of severe forms of trafficking in persons ("human trafficking") who are willing to assist law enforcement in the investigation and prosecution of human trafficking, unless unable to cooperate due to physical or psychological trauma, and who have either made a bona fide application for T nonimmigrant status that has not been denied or been granted Continued Presence (CP) from the U.S. Department of Homeland Security (DHS). The Office on Trafficking in Persons (OTIP) within the HHS Administration for Children and Families issues HHS Certification Letters that grant adult foreign victims of human trafficking eligibility for federal and state benefits and services to the same extent as refugees.

In general, OTIP initiates the certification process when it receives a notice from DHS that DHS has granted a foreign victim of trafficking CP or T nonimmigrant status, or has determined an application for T nonimmigrant status is bona fide. To issue HHS Certification Letters, it is necessary for OTIP to collect information from a victim, or a victim’s representative, such as an attorney, case manager, or law enforcement victim specialist, including an address to send the HHS Certification Letter.

OTIP will ask if the victim is in need of case management services and the current location (city, state) of the victim, and refer the victim to an appropriate service provider in his or her area, if requested. OTIP will also ask about the victim’s primary language and urgent concerns, such as medical care or housing, and transmit this information to the service provider with the victim’s consent.

Finally, OTIP reports information on victim certification to provide to Congress in an annual report on U.S. Government activities to combat trafficking that is prepared by the U.S. Department of Justice. Congress requires HHS and other appropriate Federal agencies to report information on the number of persons who received benefits or other services under subsections (b) and (f) of section 7105 of Title 22 of the U.S. Code in connection with programs or activities funded or administered by HHS. HHS may include in these annual reports additional aggregate information that it collects about the victims when assisting each victim to obtain HHS Certification.

OTIP developed the form to facilitate the submission of consistent information and improve program reporting. The trafficking victim or his or her representative may submit the completed form, which we recommend be done via password-protected email or encryption, to OTIP for the purpose of issuing a Certification Letter. OTIP will store this information in OTIP’s secure database for no longer than 10 years, at which time it will be destroyed, unless required for business use by HHS. Other details maintained in the victim’s file may include OTIP staff actions, referrals, and notes regarding the victim’s interest in receiving services. Maintaining victim records within OTIP’s database will ensure efficient service delivery for victims, allow OTIP staff to track victims’ progress toward certification, verify eligibility for benefits, and organize information for reporting aggregate data to Congress.

Respondents: Nongovernmental entities providing social or legal services, or victim/survivors of trafficking may use this form to submit a request for certification. The use of this form is optional; the victim or his/her representative has the option to make a request for certification via telephone or email.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<tr>
<td>HHS Certification Instrument</td>
<td>800</td>
<td>1</td>
<td>.5</td>
<td>400</td>
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</tbody>
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Estimated Total Annual Burden Hours: 400.

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by JUNE 22, 2018. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Doct No. FDA–2018–N–1073]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on July 12, 2018, from 8:30 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1073. The docket will close on July 11, 2018. Submit either electronic or written comments on this public meeting by July 11, 2018. Please note that late, untimely filed comments will not be considered. Written comments must be submitted on or before July 11, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 11, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 2, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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–2018–N–1073 for “Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” 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.

• 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.” FDA 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 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 the 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: AMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA’s website at https://www.fda.gov/