ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
FACES 2019 Classroom sampling form from Head Start staff	360	120	1	0.17	20
FACES 2019 Child roster form from Head Start staff	120	40	1	0.33	13
FACES 2019 Parent consent form	2,400	800	1	0.17	136
FACES 2019 Head Start parent survey	2,400	800	2	0.42	672
FACES 2019 Head Start child assessment	2,400	800	2	0.75	1,200
FACES 2019 Head Start teacher child report	240	80	20	0.17	272
FACES 2019 Head Start teacher survey	720	240	1	0.50	120
FACES 2019 Head Start program director survey	180	60	1	0.50	30
FACES 2019 Head Start center director survey	360	120	1	0.50	60
AI/AN FACES 2019 Classroom sampling form from Head Start staff	37	13	1	0.17	2
AI/AN FACES 2019 Child roster form from Head Start staff	37	13	1	0.33	4
AI/AN FACES 2019 Parent consent form	800	267	1	0.17	45
AI/AN FACES 2019 Head Start parent survey	800	267	2	0.50	267
AI/AN FACES 2019 Head Start child assessment	800	267	2	0.75	401
AI/AN FACES 2019 Head Start teacher child report	80	27	20	0.17	92
AI/AN FACES 2019 Head Start teacher survey	80	27	1	0.58	16
AI/AN FACES 2019 Head Start program director survey	22	8	1	0.33	3
AI/AN FACES 2019 Head Start center director survey	37	13	1	0.33	4

Estimated Total Annual Burden Hours: 3,357.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007)

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–18333 Filed 8–23–18; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Sponsorship Review Procedures for Approval for Unaccompanied Alien Children.

OMB No.: 0970–0278.

Description: The Administration for Children (ACF), Office of Refugee Resettlement (ORR) requests the use of emergency processing procedures in accordance with 5 CFR Section 1320.13 to expand the scope of an existing information collection under OMB control number 0970–0278, Reunification Procedures for Unaccompanied Alien Children, renamed to Sponsorship Review Procedures for Approval of Unaccompanied Alien Children. The information collection will allow ACF to conduct suitability assessments to vet potential sponsors of unaccompanied alien children in accordance with a Memorandum of Agreement (MOA) between ORR and the Department of Homeland Security. Specifically, the information collection allows ORR to obtain biometric and biographical information from sponsors, adult members of their household, and adult care givers identified in a sponsor care plan, where applicable. ORR in turn shares the information collected with other federal departments to conduct background checks. ORR intends the instruments used in this submission to be available for use by mid-May 2018.

ACF cannot reasonably comply with the normal clearance procedures because the use of normal clearance procedures is reasonably likely to prevent the collection of needed information in a timely manner. Complying with the normal clearance procedures would delay or disrupt ORR's ability to expand the background checks in order to more comprehensively evaluate the suitability of potential sponsors of unaccompanied alien children, and to ensure safe and appropriate placement of children. The information collection is essential to the mission of the agency.

Respondents: Sponsors, adult household members, parents or legal guardians of unaccompanied alien children.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Family Reunification Application	50,000	1	0.75	37,500
Authorization for Release of Information	90,000	1	0.5	45,000
Fingerprint Instructions	90,000	1	1.25	112,500

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of Designation	25,000	1	0.5	12,500

Estimated Total Annual Burden per Respondent: 207,500.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–18351 Filed 8–23–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Notice of Decision Not To Designate Pneumocystis Pneumonia as a Tropical Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), in response to suggestions submitted to Docket No. FDA–2008–N–0567, has analyzed whether *Pneumocystis* pneumonia (PCP) meets the statutory criteria for designation as a tropical disease for the purposes of obtaining a priority review voucher (PRV) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), namely whether it primarily affects poor and marginalized populations and whether there is ''no significant market'' for drugs that prevent or treat PCP in developed countries. The Agency has determined that PCP does not meet the statutory criteria for designation as a tropical disease and declines to designate it as such.

DATES: August 24, 2018.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *https://www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1300, *Katherine.Schumann@fda.hhs.gov;* or Office of Communication, Outreach and Development (OCOD), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 800–835–4709 or 240–402–8010, *ocod@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), uses a PRV incentive to encourage the development of new drugs, including biologics, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. Further information about the tropical disease PRV program can be found in guidance for industry ''Tropical Disease Priority Review Vouchers'' (81 FR 69537, October 6, 2016, available at *https://www.federalregister.gov/documents/2015/08/20/2015-20554/designating-additions-to-the-current-list-of-tropical-diseases-in-the-federal-food-drug-and-cosmetic*). Additions to the statutory list of tropical diseases published in the **Federal Register** can be accessed at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm534162.htm.*

In August 2015, FDA published a final order (80 FR 50559, August 20, 2015) (final order) designating Chagas disease and neurocysticercosis as tropical diseases. That final order also sets forth FDA's interpretation of the statutory criteria for tropical disease designation and expands the list of tropical diseases under section 524(a)(3)(R) of the FD&C Act, which authorizes the FDA to designate by order ''[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations'' as a tropical disease.

FDA has applied its August 2015 criteria as set forth in the final order to analyze whether PCP meets the statutory criteria for addition to the tropical disease list. As discussed below, the Agency has determined that PCP does not meet the statutory criteria for designation as a ''tropical disease'' and thus will not add it to the list of tropical diseases whose applications may be eligible for a priority review voucher.

II. Decision Not To Designate Pneumocystis Pneumonia

FDA has considered all diseases submitted to the public docket (FDA–2008–N–0567) between August 20, 2015, and June 20, 2018, as potential additions to the list of tropical diseases under section 524 of the FD&C Act, under the docket review process explained on the Agency's website (see