

dog from Egypt, including a dog from Egypt that is being imported from a third-party country. Such approvals will be granted on a limited and case-by-case basis and at CDC's discretion.

Individuals seeking to import a dog from Egypt must submit the Application for a Permit to Import a Dog Inadequately Immunized Against Rabies, which is currently approved under OMB Control Number 0920-0134 Foreign Quarantine Regulations (exp. 03/31/2022).

To request the advance written approval of the CDC, you must send an email to the Director, Division of Global Migration and Quarantine, at cdcanimalimports@cdc.gov, requesting an application. Once you receive instructions and the permit application, your request must be submitted at least 10 business days before the date on which you intend the dog to enter the United States. A request cannot be made at the port of entry upon arrival into the United States. As required by the permit application, your request must present sufficient, reliable evidence conclusively demonstrating that the dog you wish to import is immune from rabies. Such evidence includes a valid rabies vaccination certificate that was issued in the United States or official government documents demonstrating the reliability of the vaccine, vaccine provider, and conditions under which the vaccine was stored. The evidence you present must also demonstrate the authenticity of the documents relied upon. Your written request must further explain how you intend to establish, for example, through identifying markers, microchip, or tattoo, that the dog being imported is the same dog identified in the official government documents you provided to the CDC. If the official government documents are not written in English, then they must be accompanied by English language translations of the official government documents, the authenticity of which has been attested to by a person licensed by the government to perform acts in legal affairs.

CDC will respond to your request in writing and may impose additional conditions in granting the approval. You must present CDC's written response and approval upon entry into the United States. If your request for advance approval is denied, CDC's written denial will constitute final agency action.

VI. Terms of This Notice

Pursuant to 42 CFR 71.63 and 42 CFR 71.51(e), HHS/CDC hereby suspends, until further notice, the importation of any dog from Egypt, including dogs from Egypt that are imported from third-

party countries if the dogs have been present in those countries for less than six months. This notice will become effective on May 10, 2019, and will be remain in place subject to periodic review by the CDC until appropriate safeguards to prevent importation of CRVV from Egypt have been established.

Dated: May 6, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; State Temporary Assistance for Needy Families Case Studies (New Collection)

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

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) is proposing a data collection activity as part of the State Temporary Assistance for Needy Families (TANF) Case Studies project. This study seeks to document innovative employment and training programs for low-income individuals including TANF recipients and examine the ways the programs provide or link families to wraparound services. Over a three-year period, the study will conduct up to 12 comprehensive qualitative case studies and up to 20 profiles of innovative programs to showcase promising approaches.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing OPREinfocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests,

emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The State TANF Case Studies project will involve several phases including: (1) Identifying innovative programs through a scan of the field and engagement with stakeholders; (2) visiting up to 12 selected programs to collect detailed information and produce comprehensive case studies of these programs to enhance policymakers' and other stakeholders' understanding of promising programs helping low-income individuals to succeed in the labor force; and (3) gathering information through telephone interviews to produce up to 20 shorter case studies. The proposed information collection activities are: (1) Semi-structured interviews with program and partner administrators and frontline staff; (2) in-depth interviews with participants to better inform and enhance understanding of client experiences and perspectives; (3) a guided case review with frontline staff to capture information about client characteristics as well as intensity, frequency, duration, and sequencing of services; and (4) an observation of program services, such as case management sessions, intakes and referrals, services delivered in a classroom setting, and work sites. The study will take place over a three year period.

Respondents: Respondents include program administrators, frontline program staff, and program participants. Program administrators include staff who administer and supervise the case study program under review; TANF and employment and training programs; child care and other wraparound supports; and other workforce programs and partners such as community colleges, adult basic education providers, and employers; and state decision makers, as appropriate. Frontline program staff include intake workers, case managers, job developers, and other direct service providers who work at TANF agencies and American Job Centers, employment and training providers such as community colleges, and providers of wraparound supports, such as child care subsidy frontline staff. TANF and other low-income program participants will also be respondents. All participants will be able to opt out of participating in the data collection activities.

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
Semi-structured program staff interview guide	200	67	1	1	67
In-depth participant interview guide	24	8	1	1.5	12
Case review guide	24	8	2	.75	12

Estimated Total Annual Burden Hours: 91.

Comments: 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: Sec. 413, Pub. L. 115–31.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1798]

Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Guidance for Industry; 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 a final guidance for industry entitled “Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.” This guidance represents FDA’s current thinking on the conduct of in vivo absorption trials for topically applied active ingredients that are under consideration for

inclusion in an over-the-counter (OTC) monograph.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2019–D–1798 for “Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Guidance for Industry.” Received comments 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.” The Agency 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 to 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 this 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 dockets, 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