DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Medical Complaint Form, Contact Investigation Form: Non-TB Illness, and Contact Investigation Form: Active/Suspect TB.

OMB No.: 0970–NEW.

The Administration for Children and Families’ Office of Refugee Resettlement (ORR) places unaccompanied minors in their custody in licensed care provider facilities until reunification with a qualified sponsor. Pursuant to Exhibit 1, part A.2 of the Flores Settlement Agreement (Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al., Case No. CV 85–4544–RJK (C.D. Cal. 1996), care provider facilities, on behalf of ORR, shall arrange for appropriate routine medical and dental care, family planning services, and emergency healthcare services, including a complete medical examination within 48 hours of admission to ORR, screening for infectious diseases, appropriate immunizations in accordance with the U.S. Public Health Service (PHS), Center for Disease Control, administration of prescribed medication and special diets, and appropriate mental health interventions for each minor in care.

The Medical Complaint and Contact Investigation forms are to be used as worksheets for healthcare providers and health departments to compile information that would otherwise have been collected during a medical evaluation. Once completed, the forms will be given to care provider facility staff for data entry into ORR’s electronic data repository known as ‘The UAC Portal’. Entered data will be used to record and monitor health conditions/illnesses including infectious diseases, document preventative services, develop care plans, ensure serious illnesses/conditions receive appropriate post-release follow-up care, and to track interventions taken to prevent the spread of infectious diseases.

Respondents: Office of Refugee Resettlement Grantee staff.

Annual Burden Estimates

Estimated Respondent Burden for Responding:

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Complaint Form</td>
<td>120</td>
<td>836</td>
<td>.13</td>
<td>13,042</td>
</tr>
<tr>
<td>Contact Investigation Form: Non-TB Illness</td>
<td>120</td>
<td>4</td>
<td>.08</td>
<td>38</td>
</tr>
<tr>
<td>Contact Investigation Form: Active/Suspect TB</td>
<td>120</td>
<td>2</td>
<td>.08</td>
<td>19</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 13,099.

Annual Burden Estimates

Estimated Respondent Burden for Recordkeeping:

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Complaint Form</td>
<td>120</td>
<td>836</td>
<td>.08</td>
<td>8,026</td>
</tr>
<tr>
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<td>120</td>
<td>4</td>
<td>.08</td>
<td>38</td>
</tr>
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<td>Contact Investigation Form: Active/Suspect TB</td>
<td>120</td>
<td>2</td>
<td>.08</td>
<td>19</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden: 8,083.

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...
information in the NDNH supports OCSE’s strategic mission, goals, and objectives. OCSE will provide the annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance outcomes reports are authorized by: (1) Subsection 453 (j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets forth the terms and conditions of a computer matching program; and, (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111–352), which requires agencies to report program performance outcomes to the Office of Management and Budget and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Information collection title</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>
</tr>
</thead>
<tbody>
<tr>
<td>SNAP Matching Program Performance Outcomes</td>
<td>53</td>
<td>1</td>
<td>1.92</td>
<td>101.76</td>
</tr>
<tr>
<td>Estimated Total Annual Burden Hours:</td>
<td></td>
<td></td>
<td></td>
<td>101.76</td>
</tr>
</tbody>
</table>

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Robert Sargis,
Reports Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2475]

DETERMINATION OF REGULATORY REVIEW PERIOD FOR PURPOSES OF PATENT EXTENSION; VARUBI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VARUBI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published in the SUPPLEMENTARY INFORMATION section are incorrect may submit either electronic or written comments and ask for a redetermination by March 27, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 25, 2018. See "Petitions" in the SUPPLEMENTARY INFORMATION section for more information.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 27, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of March 27, 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.

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: