elementary and secondary students. Respondents include various components of State Human Service agencies.

Respondents: The 52 respondents include the 50 States, the District of Columbia, and Puerto Rico.

**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>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Statistical Report on Children in Foster Homes and Children Receiving Payments in Excess of the Poverty Level From a State Program Funded Under Part A of Title IV of the Social Security Act</td>
<td>52</td>
<td>1</td>
<td>264.35</td>
<td>13,746.20</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 13,746.20.

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 Sargis, Reports Clearance Officer.

[FR Doc. 2017-26353 Filed 12–6–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6476]

Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model.” This draft guidance focuses on drug development for pediatric patients with Gaucher disease. In particular, it proposes for consideration a novel approach to improve the efficiency of drug development in pediatric rare diseases using Gaucher disease as an example. The emergence of concomitant trials for multiple investigational drug products for the treatment of rare diseases can pose significant challenges to effective drug development, because there are limited numbers of patients for any given rare condition worldwide. This approach discusses the feasibility of the development of multiple drug products in a time-efficient manner while minimizing the number of patients necessary to be treated with placebo.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronically:

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 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–2017–N–6476 for “Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry; Availability.” 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 office 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
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model.” The emergence of concomitant trials for multiple investigational drug products for the treatment of rare disease can pose significant challenges to effective drug development, given the limited number of patients worldwide with these diagnoses. This guidance discusses, among other things, a multi-arm, multi-company clinical trial as a novel approach to enhance the efficiency of drug development in pediatric rare diseases using pediatric Gaucher disease as an example. The proposal applies only to systemic (i.e., non-neurological) manifestations of Gaucher disease (i.e., patients with Type I and Type III phenotypes).

The purpose of this guidance is to facilitate drug development in pediatric rare diseases, with a focus on Gaucher disease. In this guidance, Gaucher disease is provided as a disease model. However, the principles underlying this proposal may be extended to other areas of drug development in rare diseases.

The guidance was originally a document developed as a strategic collaboration between FDA and the European Medicines Agency to enhance the efficiency of drug development in Gaucher disease, which was released in 2014 for public comment. The draft guidance is an updated version of the document and has no fundamental changes to the original intent and content.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model.” It does not establish any requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR 201.57 for the content and format of prescription drug labeling was approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/...