### ANNUAL BURDEN ESTIMATES

<table>
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<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hour per response</th>
<th>Total burden hours</th>
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<tbody>
<tr>
<td>New Program Specific PPRs</td>
<td>600</td>
<td>2</td>
<td>4</td>
<td>4,800</td>
</tr>
</tbody>
</table>

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Administration for Community Living

**Request for Information: Family Caregiving & Grandparents Raising Grandchildren.**

In addition, the title of the notice in order to avoid confusion for potential commenters.

**SUMMARY:** The Administration for Community Living (ACL) published a document in the Federal Register on December 9, 2019, requesting information to the Advisory Council to Support Grandparents Raising Grandchildren seeking information to be used in the development of the Initial Report, as required by the Supporting Grandparents Raising Grandchildren Act (SGRG). The ACL wishes to change a line in the titling of the notice in order to avoid confusion for potential commenters.

**SUPPLEMENTARY INFORMATION:**

Correction: In the Federal Register of December 9, 2019, in FR doc. 2019–26437, on page 67270, in the second column, the second line should be changed to “Request for Information: Advisory Council to Support Grandparents Raising Grandchildren.” In addition, the DATES section due date is incorrect. It should read as follows:

**DATES:** Comments on the request for information must be submitted by 11:59 p.m. (EST) on February 7, 2019.

**FOR FURTHER INFORMATION CONTACT:**

SGRG.Acct@acl.hhs.gov

Dated: December 9, 2019.

**Lance Robertson,**

Administrator and Assistant Secretary for Aging.

[FR Doc. 2019–26880 Filed 12–12–19; 8:45 am]

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

**Food and Drug Administration Reauthorization Act Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs; Draft Guidance for Industry; Availability**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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs.” This guidance addresses early planning for pediatric evaluation of certain molecularly targeted oncology drugs, including biological products, for which original new drug applications (NDAs) and biologics license applications (BLAs) are expected to be submitted to FDA on or after August 18, 2020, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the FDA Reauthorization Act of 2017 (FDARA). This guidance addresses the implementation of amendments made by FDARA to the FD&C Act regarding molecularly targeted oncology drugs.

**DATES:** Submit either electronic or written comments on the draft guidance by February 11, 2020, 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:

**Electronic Submissions**

Submit electronic comments in the following way:

- Federal eRulemaking Portal: [https://www.regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://www.regulations.gov](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](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–4751 for “FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at [https://www.regulations.gov](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/
fsys/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.
You may submit comments on any
guidance at any time (see 21 CFR
10.115(g)(5)). Submit written requests
for single copies of the draft guidance to
the Office of Communication, Outreach
and Development, Center for Biologics
Evaluation and Research (CBER), Food
and Drug Administration, 10903 New
Hampshire Ave., Bldg. 71, Rm. 3128,
Silver Spring, MD 20993–0002; Division
of Drug Information, Center for Drug
Evaluation and Research (CDER), Food
and Drug Administration, 10001 New
Hampshire Ave., Hillandale Building,
4th Floor, Silver Spring, MD 20993–
0002. Send one self-addressed adhesive
label to assist that office in processing
your requests. The draft guidance may
also be obtained by mail by calling
CBER at 1–800–835–4709 or 240–402–
8010. See the SUPPLEMENTARY
INFORMATION section for electronic
access to the draft guidance document.
FOR FURTHER INFORMATION CONTACT:
Gregory Reaman, Oncology Center of
Excellence, Food and Drug
Administration, 10903 New
Hampshire Ave., Bldg. 22, Rm. 2202, Silver Spring,
MD 20993–0002, 301–796–0785; or
Stephen Ripley, Center for Biologics
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 71, Rm. 7301,
Silver Spring, MD 20993–0002, 240–
402–7911.
SUPPLEMENTARY INFORMATION:
I. Background
FDA is announcing the availability of
a draft guidance for industry entitled
“FDARA Implementation Guidance for
Pediatric Studies of Moleculary
Targeted Oncology Drugs: Amendments
to Sec. 505B of the FD&C Act.” This
draft guidance addresses early planning
for pediatric evaluation of certain
molecularly targeted oncology drugs
(including biological products) for
which original NDAs and BLAs are
expected to be submitted to FDA on or
after August 18, 2020, in accordance
with the provisions of section 505B of
the FD&C Act. Section 505B of the
FD&C Act (21 U.S.C. 355c) (also referred
to as the Pediatric Research Equity Act
or PREA (Pub. L. 108–155)), was
amended by FDARA.
The amendments provide a new
mechanism to expedite the evaluation of
certain novel drugs with the potential to
address an unmet medical need of
pediatric patients with cancer.
Specifically, FDARA amended the
requirement for pediatric investigations
of certain new targeted cancer drugs to
be based on molecular mechanism of
action rather than clinical indication.
For original NDAs and BLAs submitted
on or after August 18, 2020, if the
application is for a new active
ingredient, and the drug or biological
product that is the subject of the
application is intended for treatment of
an adult cancer and directed at a
molecular target FDA determines to be
substantially relevant to the growth or
progression of a pediatric cancer,
reports of molecularly targeted pediatric
cancer investigations must be submitted
with the marketing application, unless
the required investigations are waived
or deferred (section 505B(a)(1)(B) of
the FD&C Act).
This draft guidance provides
recommendations on regulatory
considerations related to the
amendments to section 505B of the
FD&C Act, including information on
molecular targets, factors FDA intends
to consider in the determination of
whether a molecular target is
substantially relevant to the growth or
progression of a pediatric cancer, the
molecular target lists, content of the
initial pediatric study plan and
description of recommended studies,
additional considerations for rare
cancers, and considerations for planned
waivers and deferrals. In addition, the
draft guidance includes information
regarding global implications and
international collaboration.
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 “FDARA Implementation Guidance
for Pediatric Studies of Moleculary
Targeted Oncology Drugs.” It does not
establish any rights for any person and
is not binding on FDA or the public.
You can use an alternative approach if
it satisfies the requirements of the
applicable statutes and regulations.
II. 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. 3501–3521). The collections
of information in 21 CFR part 314 have
been approved under OMB control
number 0910–0001. The collections
of information in 21 CFR part 312 have
been approved under OMB control
numbers 0910–0014. The collections
of information in 21 CFR part 601 have
been approved under OMB control
number 0910–0338.
III. Electronic Access
Persons with access to the internet
may obtain the draft guidance at either
https://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm, https://
www.fda.gov/BiologicsBloodVaccines/
GuidanceComplianceRegulatory
Information/Guidances/default.htm, or
Dated: December 9, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019–26877 Filed 12–12–19; 8:45 am]
BILLING CODE 4164–01–P
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Health Resources and Services
Administration
Agency Information Collection
Activities: Submission to OMB for
Review and Approval; Public Comment
Request; Bureau of Primary Health
Care Uniform Data System, OMB No.
0915–0193—Revision
AGENCY: Health Resources and Services
Administration (HRSA), Department of
Health and Human Services (HHS).