ANNUAL BURDEN ESTIMATES

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<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hour per response</th>
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Draft Guidance for Industry;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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs; Draft Guidance for Industry; Availability.” This draft guidance addresses early planning for pediatric evaluation of certain molecularly targeted oncology drugs, including biological products, for which original new drug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DATES: Submit either electronic or written comments on the draft guidance by February 11, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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. 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.

Confidential Submissions—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 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...