

reauthorization of the Head Start program (Pub. L. 110-134), which calls

for periodic assessments of Head Start's quality and effectiveness.

Respondents: Head Start children, parents of Head Start children, and Head Start teachers and Head Start staff.

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
FACES 2019 Classroom sampling form from Head Start staff	360	120	1	0.17	20
FACES 2019 Child roster form from Head Start staff	120	40	1	0.33	13
FACES 2019 Parent consent form	2,400	800	1	0.17	136
FACES 2019 Head Start parent survey	2,400	800	2	0.42	672
FACES 2019 Head Start child assessment	2,400	800	2	0.75	1,200
FACES 2019 Head Start teacher child report	240	80	20	0.17	272
FACES 2019 Head Start teacher survey	720	240	1	0.50	120
FACES 2019 Head Start program director survey	180	60	1	0.50	30
FACES 2019 Head Start center director survey	360	120	1	0.50	60
AI/AN FACES 2019 Classroom sampling form from Head Start staff	37	13	1	0.17	2
AI/AN FACES 2019 Child roster form from Head Start staff	37	13	1	0.33	4
AI/AN FACES 2019 Parent consent form	800	267	1	0.17	45
AI/AN FACES 2019 Head Start parent survey	800	267	2	0.50	267
AI/AN FACES 2019 Head Start child assessment	800	267	2	0.75	401
AI/AN FACES 2019 Head Start teacher child report	80	27	20	0.17	92
AI/AN FACES 2019 Head Start teacher survey	80	27	1	0.58	16
AI/AN FACES 2019 Head Start program director survey ...	22	8	1	0.33	3
AI/AN FACES 2019 Head Start center director survey	37	13	1	0.33	4

Estimated Total Annual Burden Hours: 3,357.

Authority: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE-157 Child Support Enforcement Program Annual Data Report.

OMB No.: 0970-0177.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by

law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs.

OCSE is proposing updates to the OCSE-157 report instructions to update and clarify reporting requirements. Respondents are encouraged to contact the agency to obtain a copy of the revised instructions for review and comment.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-157	54	1	7	378

Estimated Total Annual Burden Hours: 378.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3380]

Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products; 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 “Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.” This draft guidance describes considerations for the development and labeling of *in vitro* companion diagnostic devices (referred to as *companion diagnostics* in this document) to support the indicated uses of multiple drug or biologic oncology products (referred to as *therapeutic products* or *oncology therapeutic products* in this document), when appropriate. The draft guidance includes factors for considering when broader labeling (*i.e.*, labeling that is expanded) of a companion diagnostic would be appropriate. Oncology companion diagnostics with broader evidence-based indications will optimally facilitate clinical use.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 2019 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>.

- 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-2018-D-3380 for “Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.” 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 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Division of Drug Information, Center for Drug Evaluation and Research, 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 FDA's Center for Biologics Evaluation and Research (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: 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; Reena Philip, Center for