

use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.⁴ And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.⁵ And I agree with the observation of my colleague Commissioner Chopra in his statement that “[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ‘a competitor’s ability to compete’ on honest attributes.”⁶ Although I support these cases, I hope that the Commission’s actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Formative Data Collections for ACF Program Support (OMB #0970-0531)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) proposes to revise the existing overarching generic clearance for Formative Data Collections for ACF Program Support (OMB #0970-0531) to increase the estimated number of respondents and, therefore, the overall burden estimate.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The goals of the generic information collections under this approval are to obtain information about program and grantee processes or needs,

and to inform the following types of activities, among others:

- Delivery of targeted assistance and workflows related to program and grantee processes, and the development and refinement of recordkeeping and communication systems.
- Planning for provision of programmatic or evaluation-related training or technical assistance (T/TA).
- Obtaining grantee or other stakeholder input on the development of program performance measures.
- Use of rapid-cycle testing activities to strengthen programs in preparation for summative evaluations.

ACF uses a variety of techniques such as semi-structured discussions, focus groups, surveys, templates, open-ended requests, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Respondents: Example respondents include: Current or prospective service providers, training or T/TA providers, grantees, contractors, current and potential participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF programs, key stakeholder groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, or others involved in or prospectively involved in ACF programs.

| Instrument | Estimated total number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|---------------------------------------|------------------------------------|-----------------------------------|---------------------|
| Semi-Structured Discussions and Focus Groups | 5,000 | 1 | 2 | 10,000 |
| Interviews | 2,500 | 1 | 1 | 2,500 |
| Questionnaires/Surveys | 2,500 | 1.5 | .5 | 1,875 |
| Templates and Open-ended Requests | 650 | 1 | 10 | 6,500 |

⁴ See FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>.

⁵ See, e.g., Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), <https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health>; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin*

Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC (Dec. 2014), <https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin>; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), <https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru>; Statement of Commissioner Maureen K. Ohlhausen *Dissenting in Part and Concurring in Part, In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), <https://www.ftc.gov/public-statements/2014/01/>

statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; *Dissenting Statement of Commissioner Maureen K. Ohlhausen, FTC v. Springtech 77376, et al.* (July 2013), <https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen>; see also J. Howard Beales, III and Timothy J. Muris, *In Defense of the Pfizer Factors*, *George Mason Law & Economics Research Paper No. 12-49* (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

⁶ See Statement of Commissioner Rohit Chopra *Regarding the Cannabidiol (CBD) Enforcement Actions* (Dec. 17, 2020).

Estimated Total Annual Burden Hours: 20,875.

Authority: Social Security Act, Sec 1110 [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1440]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 9, 2021, from 10 a.m. to 2 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1440. The docket will close on February 8, 2021. Submit either electronic or written comments on this public meeting by February 8, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 8, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 8, 2021. 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.

Comments received on or before January 26, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2020–N–1440 for “Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received

comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- **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.” FDA 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 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 the 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously