ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Individuals in racial and ethnic groups.	Survey Screener Questionnaire	1,500	1	2/60	50
LGBTQ+ individuals	Survey Screener Questionnaire	1,125	1	2/60	38
General population	Community Web-Panel Survey	4,050	1	30/60	2,025
Individuals in racial and ethnic groups.	Community Web-Panel Survey	600	1	30/60	300
LGBTQ+ individuals	Community Web-Panel Survey	450	1	30/60	225
General population	Focus Group Screener Questionnaire.	34	1	3/60	2
Individuals in racial and ethnic groups.	Focus Group Screener Questionnaire.	33	1	3/60	2
LGBTQ+ individuals	Focus Group Screener Questionnaire.	33	1	3/60	2
General population	Community Focus Group	25	1	1	25
Individuals in racial and ethnic groups.	Community Focus Group	25	1	1	25
LGBTQ+ individuals	Community Focus Group	25	1	1	25
Total	.....	.....	.....	.....	3,047

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–12358 Filed 6–8–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Medical Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970–0509); Correction

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments; correction.

SUMMARY: The Administration for Children and Families (ACF) published a document in the **Federal Register** of June 1, 2023, concerning request for comments on a 3-year extension of the *Mental* Health Assessment Form (formerly the Health Assessment Form) and Public Health Investigation Forms, Active Tuberculosis (TB) and Non-TB Illness (Office of Management and Budget (OMB) #0970–0509, expiration December 31, 2023). The published notice contained an incorrect title and a typo in the *Description* section.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 1, 2023, in FR Doc. 2023–11627, the following corrections apply:

1. On page 35879, in the third column, the correct title is: Proposed Information Collection Activity; Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970–0509).

2. On page 35880 in the third column, there is a typo in the second sentence. The sentence should read: In addition, ORR has written an instructional letter for the Mental Health Assessment Form to explain the purpose of the form and provide general guidance on completion to healthcare providers.

DATES: Comments due on the information collection proposed in 88 FR 35879 on or before July 31, 2023.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–12334 Filed 6–8–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1848]

Clinical Drug Interaction Studies With Combined Oral Contraceptives; 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 final guidance for industry entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' This guidance is intended to help sponsors of investigational new drug applications and new drug applications evaluate the need for drug-drug interaction (DDI) studies with combined oral contraceptives (COCs), design such studies, and determine how to communicate DDI study results and risk mitigation strategies to address potential risks associated with increased or decreased exposure of COCs in labeling. The guidance finalizes the draft guidance ''Clinical Drug Interaction Studies With Combined Oral Contraceptives'' issued on November 23, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 9, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–1848 for ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' 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, 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.'' 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.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Xinning Yang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301–796–7412, *Xinning.Yang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' COCs can effectively prevent pregnancy; however, the use of concomitant medications could result in DDIs that affect the safety and/or efficacy of COCs. For example, the induction of drug metabolizing enzymes could cause lower levels of progestin and/or estrogen and compromise the efficacy of COCs, while inhibition of metabolizing enzymes could cause higher levels of these hormones and increase the risk of safety events, such as venous thromboembolism. This guidance discusses when clinical DDI studies with COCs should be conducted. It also provides recommendations on the design and conduct of such studies, including but not limited to, the study population, the choice of COC, study design, pharmacokinetic sampling schedule, and pharmacodynamic assessments. In addition, this guidance discusses the interpretation of results from clinical DDI studies with COCs and whether it is possible to extrapolate the results of such studies to other COCs. This guidance also provides recommendations to sponsors on communicating DDI study results and risk mitigation strategies in labeling to address potential risks associated with increased or decreased exposure of COCs. A decision tree regarding whether a DDI study with a COC is recommended based on the metabolizing enzyme inhibition or induction potential of the investigational drug is also included.

This guidance finalizes the draft guidance entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives'' issued on November 23, 2020 (85 FR 74737). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the addition of more explanations/scenarios when a DDI study with COCs may or may not be recommended, clarifications for non-teratogenic drugs that are intended to be used as a combination therapy with teratogenic drugs, removal of food intake recommendations, addition of alternative options for choosing COCs, and more examples of pharmacodynamic parameters for the DDI study.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologic license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 pertaining to the content and format of labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12370 Filed 6–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3343]

Advisory Committee; Dermatologic and Ophthalmic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Dermatologic and Ophthalmic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2024, expiration date.

DATES: Authority for the Dermatologic and Ophthalmic Drugs Advisory Committee will expire on October 7, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, *DODAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of nine voting members including two Chairpersons. Members and the Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/dermatologic-and-ophthalmic-drugs-advisory-committee/dermatologic-and-ophthalmic-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12293 Filed 6–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Communication Disorders Review Committee, which was published in the **Federal Register** on May 01, 2023, FR DOC 2023–09130, 88 FR 26579.

This notice is being amended to change the meeting location from Embassy Suites at Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 to Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852. The meeting is closed to the public.

Dated: June 5, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–12326 Filed 6–8–23; 8:45 am]

BILLING CODE 4140–01–P