

Desk Officer for the Administration for Children and Families.

Emily B. Jabbour,
ACF/OPRE Certifying Officer.

[FR Doc. 2018-17121 Filed 8-9-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects

Title: Supplemental Nutrition Assistance Program (SNAP) Matching Program Performance Outcomes.

OMB No. 0970-0464.

Description: State agencies administering the Supplemental Nutrition Assistance Program (SNAP) are mandated to participate in a

computer matching program with the federal Office of Child Support Enforcement (OCSE). The matching program compares SNAP applicant and recipient information with employment and wage information maintained in the National Directory of New Hires (NDNH). The outcomes of the compared information help state SNAP agencies with administering the program and verifying and determining an individual's benefit eligibility. To receive NDNH information, state agencies enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSE with annual performance outcomes attributable to the use of NDNH information.

The Office of Management and Budget (OMB) requires OCSE to periodically report performance measurements demonstrating how the use of information in the NDNH supports OCSE's strategic mission, goals, and objectives. OCSE will provide the

annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance outcomes reports are authorized by: (1) Subsection 453(j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets forth the terms and conditions of a computer matching program; and, (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111-352), which requires agencies to report program performance outcomes to the Office of Management and Budget and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Information collection title	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SNAP Matching Program Performance Outcomes	53	1	1.92	101.76

Estimated Total Annual Burden Hours: 101.76.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 330 C Street SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

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.

[FR Doc. 2018-17152 Filed 8-9-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2582]

Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the following 1-day public workshop entitled "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation." The purpose of the public workshop is to provide a forum to discuss the current state and future directions of the collection of human data on the potential skin toxicity with the use of medications applied topically. The workshop will review current approaches to the collection of human data during the clinical development of topical drug products. The workshop will also address the

impact of human skin toxicity studies on drug labeling and consider alternative approaches to providing information about skin toxicity.

DATES: The public workshop will be held on September 10, 2018, from 8:30 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by October 10, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 10, 2018. The

<https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 10, 2018. 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.

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-N-2582 for "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; 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.

- **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.

FOR FURTHER INFORMATION CONTACT: Tisha Washington, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1019, tisha.washington@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop entitled "Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation" to discuss the current state and future directions of the collection of human data on the potential skin risks

from use of topical drug products, including irritancy, sensitization, phototoxicity, and photoallergenicity.

II. Topics for Discussion at the Public Workshop

The morning session of the workshop will focus on review and discussion of current approaches for the collection of human skin toxicity data, limitations of these approaches, and their impact on labeling of topical drug products. The afternoon session of the workshop will be a panel discussion by individuals with different perspectives about alternative approaches to provide information about skin toxicity. Thirty minutes of the afternoon session will be allocated to an open public hearing. The Agency encourages health care providers, industry representatives, and other interested persons to attend this public workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website by September 4, 2018: <https://www.eventbrite.com/e/fda-public-workshop-human-dermal-safety-testing-for-topical-drug-products-tickets-47483161414>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone, and intended attendance method—in person or by webcast. You may also indicate if you wish to present at the public comment session (see *Requests for Oral Presentations*). For those unable to attend in person, FDA will provide a live webcast of the workshop.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 5 p.m. Eastern Time, September 4, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Seating will be available on a first-come, first-served basis. If time and space permit, onsite registration on the day of the workshop will be provided beginning at 8:15 a.m. Eastern Time; FDA will let the public know whether onsite registration is available before the day of the public workshop.

An agenda for the workshop and any other background materials will be made available 5 days before the workshop at <https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm>.

If you need special accommodations due to a disability, please contact Tisha

Washington, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1019, tisha.washington@fda.hhs.gov no later than September 4, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present at the public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 5, 2018. All requests to make oral presentations must be received by the close of registration on September 4, 2018. If selected for presentation, any presentation materials must be emailed to Tisha Washington (see **FOR FURTHER INFORMATION CONTACT**) no later than close of business, September 6, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the following web page 5 days before the workshop at: <https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm611203.htm>.

Dated: August 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-17130 Filed 8-9-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

HHS Approval of Entities That Certify Medical Review Officers

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice publishes a list of the Department of Health and Human Services (HHS) approved Medical Review Officers certification entities. The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), applicable on October 1, 2017, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

FOR FURTHER INFORMATION CONTACT:

Sean J. Belouin, Pharm.D., CAPT, United States Public Health Service, Senior Pharmacology and Regulatory Policy Advisor, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 16N06D, Rockville, Maryland 20857; Telephone: (240) 276-2716; Email: sean.belouin@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: Subpart M—Medical Review Officer (MRO), Section 13.2 of the Mandatory Guidelines, “How are nationally recognized entities or subspecialty boards that certify MROs approved?” states as follows: “All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (e.g., answers, previous examination statistics or other background examination information, if requested) (OMB Control No.: 0930-0158). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must

resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the internet at <http://www.samhsa.gov/workplace/drug-testing>.”

HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS.

The HHS Secretary approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, Phone: (919) 489-5407, Fax: (919) 490-1010, Email: bbrandon@aamro.com, website: <http://www.aamro.com/>.

Medical Review Officer Certification Council (MROCC), 3231 S. Halsted St., #167, Chicago, IL 60608, Phone: (847) 631-0599, Fax: (847) 483-1282, Email: mrocc@mrocc.org, website: <http://www.mrocc.org/>.

DATES: HHS approval is effective July 31, 2018.

Alex M. Azar II,
Secretary.

[FR Doc. 2018-17184 Filed 8-9-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,