

inspecting laboratories are equivalent to those required under our regulations for laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. Therefore, we have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Subpart J—Facility Administration for Nonwaived Testing

We have determined that COLA's requirements for the specialty of Histocompatibility are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

Subpart K—Quality System for Nonwaived Testing

We have determined that COLA's requirements for the specialty of Histocompatibility are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299.

Subpart M—Personnel for Nonwaived Testing

We have determined that COLA's requirements for the specialty of Histocompatibility are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

Subpart Q—Inspection

We have determined that COLA's requirements for the specialty of Histocompatibility are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780.

Subpart R—Enforcement Procedures

We have determined that COLA's requirements for the specialty of Histocompatibility meet the requirements of subpart R to the extent that it applies to accreditation organizations. COLA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, COLA will deny, suspend, or revoke accreditation in a laboratory accredited by COLA and report that action to us within 30 days. COLA also provides an appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that COLA's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493

subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by COLA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

CLIA regulations at § 493.575 provide that we may withdraw the approval of an accreditation organization, such as that of COLA, before the end of the effective date of approval in certain circumstances. For example, if we determine that COLA has failed to adopt or maintain requirements that are equal to, or more stringent than, the CLIA requirements, or that widespread or systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which COLA would be allowed to address any identified issues. Should COLA be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, withdraw COLA's deeming authority under CLIA.

Should circumstances result in our withdrawal of COLA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB control number 0938-0686.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and

approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970-0617]

Proposed Information Collection Activity; Administration for Children and Families Generic for Information Collections Related to Gatherings

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services intends to request approval from the Office of Management and Budget (OMB) for extension of an approved generic clearance to request information from potential participants at ACF gatherings, such as meetings or conferences. The current expiration date is September 30, 2026. Burden estimates have been updated to reflect agency plans over the next three years.

DATES: *Comments due August 10, 2026.*

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. 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.

SUPPLEMENTARY INFORMATION:

Description: ACF hosts a variety of gatherings for many different purposes. This may include large scale conferences, meetings for grantees or contractors, workshops, trainings, poster sessions, and other in-person and virtual gatherings for individuals with interest in ACF programs (clients, researchers, policymakers, etc.), among others. To ensure ACF has adequate information to plan these activities, the

Agency must often collect information from potential participants such as basic contact information, preferences for attendance (mode, special requests, etc.), organizational affiliation, feedback about meeting content, etc. Additionally, some activities require ACF to have additional information to have the means to select the most appropriate participants for attendance according to the type or purpose of a given activity, or to group participants into the most appropriate category or activity during an event. This may include information about poster presentations, speaking panels, training courses, professional perspectives, or experiences, etc. In addition, attendees may be asked to submit an application or abstract for prescreening to be selected for attendance.

The planning for these gatherings is often on a quick timeline, request similar information, are low burden and don't raise substantive or policy issues. Therefore, ACF established an umbrella generic under the PRA to allow ACF to quickly receive review and approval for proposed collections that fit within the scope of the umbrella generic.

The purposes of the collections under this umbrella generic are to gather appropriate information to plan ACF

gatherings. Example information collection activities could include:

- Registration forms
 - Information collected on these types of forms could include name, contact information, organization/affiliation, basic demographics, attendance needs, etc.
- Applications for panels, posters, or other presentation formats
 - Information collected on these types of applications could include title, author(s), institution/organization, abstract describing presentation or poster, instructions, etc.
- Pre-meeting surveys
 - Information collected on these types of surveys could include content preferences, scheduling needs and preferences, pre-meeting knowledge, etc.
- Post-Meeting/-Workshop/-Training Evaluation Surveys
 - Information collected on these types of surveys could include requests for feedback on the overall activity, feedback on content, post-meeting knowledge, post-meeting uses of content, preferences for future activities, etc.

As part of this generic, ACF requests OMB provide a response on individual

generic information collections within 5 business days.

Note that this generic is primarily for information collected in connection with closed ACF meetings, as information collected in connection with public ACF meetings are not considered "information" under PRA per 44 U.S.C., 5 CFR Ch. 11 (1–199 Edition), 1320.3: Definitions. Currently approved individual requests can be found here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202605-0970-006.

Respondents: Potential respondents may include researchers, individuals with expertise in ACF program areas, individuals with interest in ACF program areas, those receiving ACF services, ACF grantees or contractors, among others with involvement or interest in ACF activities.

Annual Burden Estimates—New Requests

The estimated annual burden for the next three years is about 54 percent less than the estimated annual burden hours originally approved for this overarching generic. This is based on use over the past three years and expectations for the next three years, with a focus on efforts to reduce burden across ACF.

New types of information collections	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Total annual burden hours
Registration Forms, Applications, Pre-and Post- activity Surveys, Other Activities	35,167	1	0.1296	4,558

Annual Burden—Approved Ongoing Requests

The following table includes approved information collections under

this umbrella generic that are ongoing and will be included for extension.

Ongoing information collections	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Administration for Native Americans Registration Form	300	1	0.167	50
Children's Bureau's National Child Welfare Center for Innovation and Advancement, Non-Public Event Registration	6,475	1	0.050	324
National Center on Substance Abuse and Child Welfare Communities of Practice Registration Information Collection	220	1	0.068	15
National Center on Substance Abuse and Child Welfare Convening Attendee Recommendation Information Collection	100	1	0.080	8
National Center on Substance Abuse and Child Welfare Convening Registration Information Collection	105	1	0.057	6
National Center on Substance Abuse and Child Welfare Grantee Meeting Registration Information Collection	300	1	0.033	10
National Center on Substance Abuse and Child Welfare Learning Exchange Registration Information Collection	350	1	0.083	29
National Center on Substance Abuse and Child Welfare Policy Academy Meeting and Training Registration Information Collection	1000	1	0.033	33
National Center on Substance Abuse and Child Welfare Site Visit Registration Information Collection	650	1	0.083	54
National Center on Substance Abuse and Child Welfare Training Registration Information Collection	785	1	0.066	52

Ongoing information collections	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
2026 Native Communities Home Visiting Meeting	580	1	0.210	122
Tribal Maternal, Infant, and Early Childhood Home Visiting (TMIECHV) Kickoff Meeting Registration	20	1	0.100	2
Fiscal Responsibility Act Outcomes Working Group Interest Form	50	1	0.080	4
Child Care Quality and Business Support Center, Events Registration Questions	7360	1	0.032	242
Office of Child Care Events Registration and Post-Event Survey	4500	1.75	0.064	506
Office of Child Care National Tribal Conference Registration Questions	400	1	0.083	33
Office of Child Care Regional Meeting Registration Questions	330	1	0.082	27
Office of Child Care State and Territory Administrator's Meeting Registration Questions	400	1	0.082	33
Office of Child Care Tribal Child Care and Development Fund (CCDF) Plan Training	630	1	0.084	53
Office of Child Care Tribal Cluster Meeting Registration Questions	190	1	0.084	16
Registration for National Center on Subsidy Innovation and Accountability Events	1000	1	0.033	33
Community Economic Development Grant Recipient Conference	200	1	0.229	96
Head Start Registration Form Questions	34,000	1	0.017	567
Sum Totals:	59,945			2,315

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6494]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: In response to an over-the-counter (OTC) monograph order request (OMOR), the Food and Drug

Administration (FDA) is announcing the availability on its website of the final administrative order (final order) (OTC000039) titled "Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information." This final order amends "Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use" (OTC Monograph M020) to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. A sunscreen drug product containing bemotrizinol is generally recognized as safe and effective (GRASE) if it meets the conditions described in OTC Monograph M020 as amended by this final order.

DATES: The announcement of the availability on FDA's website of the final order is published in the **Federal Register** on June 10, 2026.

ADDRESSES: For access to final order OTC000039, go to the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. See the **SUPPLEMENTARY INFORMATION** section for more information on electronic access to the final order.

FOR FURTHER INFORMATION CONTACT: Shannon Liu, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-2484, Shannon.Liu@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing final order OTC000039 to amend the requirements for sunscreen drug products for OTC human use, as described in OTC Monograph M020, to add bemotrizinol for use as a sunscreen active ingredient at concentrations up to 6 percent. FDA is issuing the final order pursuant to section 505G(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(1)).

OTC Monograph M020 describes the conditions under which OTC sunscreen drug products are GRASE under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). OTC Monograph M020 was previously set forth in final order OTC000006, as deemed by sections 505G(b)(8) and 505G(k)(2)(B) of the FD&C Act, and was effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) on March 27, 2020. The conditions described in OTC Monograph M020 may be amended, revoked, or otherwise modified in accordance with the procedures of section 505G(b) of the FD&C Act.

On September 23, 2024, DSM Nutritional Products LLC submitted a Tier 1 OMOR requesting FDA issue an administrative order finding that a sunscreen drug product containing bemotrizinol as an active ingredient is GRASE under the conditions described in OTC Monograph M020.

Final order OTC000039 amends the conditions described in OTC Monograph M020, as set forth in final order OTC000006, to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. The final