DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0447]

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices,'' published in the **Federal Register** of June 18, 2014. FDA is reopening the comment period in response to a request for additional time and to allow interested persons more time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments by October 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding human prescription biological products: 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.

Regarding animal prescription drugs: Thomas Moskal, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 18, 2014 (79 FR 34760), FDA announced the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices.'' In that document, FDA requested comments on the draft guidance, which responds to (among other things) stakeholder requests for specific guidance. The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or cleared products when that information is created or disseminated by independent third parties. The draft guidance also updates and clarifies FDA's policies on the correction of misinformation created or disseminated by independent third parties on the Internet or through social media platforms, regardless of whether that misinformation appears on a firm's own forum, an independent third-party forum, or a Web site. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA actively continues to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

Interested persons were originally given until September 16, 2014, to submit comments on the draft guidance.

II. Request for Comments

Following publication of the June 18, 2014, notice, FDA received a request for additional time to develop meaningful and thoughtful comments, especially in light of the concurrent comment period with another draft guidance entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices'' published elsewhere in this volume of the **Federal Register**.

FDA has considered the request and will reopen the comment period for an additional 30 days. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23064 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Final Policy on Conferring With Urban Indian Organizations

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS or ''the Agency'') is issuing this Notice to implement the final Policy for conferring with Urban Indian Organizations (UIOs). In March 2010, the Indian Health Care Improvement Act (IHCIA) was reauthorized and amended as part of the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act (together, the Affordable Care Act), Public Law 111–152. One of the changes made to the IHCIA was to create a new requirement that the IHS ''confer'' with UIOs, to the maximum extent practicable, in carrying out the IHCIA.

DATES: This Policy will become effective on October 29, 2014.

FOR FURTHER INFORMATION CONTACT: Office of Management Services, Management Policy and Internal Control Staff, Indian Health Service, 801 Thompson Avenue, Suite 625A, Rockville, Maryland 20852. Telephone 301/443–2650 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The IHS published a proposed draft Policy in a notice in the **Federal Register** on July 26, 2012 (77 FR 43846). In response to the notice, the Agency received thirty-two comments on the draft Policy. All comments were considered and appropriate changes were made to the policy. In addition, a Listening Session was held on January 22, 2013, following publication of a meeting notice in the **Federal Register** (78 FR 2413).

Inspection of Public Comments

Comments are available for public inspection at the following address: Indian Health Service, Division of Regulatory Affairs, 12300 Twinbrook Parkway, TMP Suite 430, Rockville MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1–301–443–1116 (not a toll free number).

Summary and Discussion of Comments Received

The Agency received thirty-two comments on the draft Policy. All comments were considered and appropriate changes were made to the policy. Fifteen of the comments were in support of the Policy as it was written. Numerous comments addressed topics that would require no change to the Policy; however, some comments did raise critical issues that may require additional conferring activities. It is expected that the confer process may result in the need to update this policy from time to time.

Several commenters recommended that UIOs confer with the respective Area Offices rather than with Service Units. The Policy identifies a conferring role to be available at every level of IHS, including both Area Offices and Service Units, if applicable. UIOs are not limited or required to confer at any specific level. IHS will conduct special trainings and provide technical assistance for the Service Units, if necessary.

One commenter recommended that application of the Federal Advisory Committee Act (FACA) be clarified. The policy is updated to clarify the applicability of FACA when federal advisory groups are convened for the purpose of generating consensus recommendations, and the inapplicability of the ''intergovernmental'' exemption. In the event questions arise regarding application of FACA, the following was added at the end of the FACA section in the Policy: ''For questions regarding the applicability of FACA, please contact the Director, IHS Division of Regulatory Affairs, Office of Management Services.''

Several commenters were concerned about the authority in the draft Policy for the Director, IHS, and the Director, Office of Urban Indian Health Programs, to determine when to confer, and expressed objection to the proposal to require conference between the IHS and UIOs upon the occurrence of a critical event as determined by IHS, and further commented that either party should be able to identify a critical event. In response to the comments, IHS removed the subject language from the final Policy. Consistent with the IHCIA, the Policy requires IHS to confer, to the maximum extent practicable, on any critical event or issue, which is defined broadly as ''an event or issue that significantly affects one or more UIOs.'' Section 5–26.4(A) provides that a critical event or issue may be identified by IHS and/or UIOs. Subsection (A)(2) was amended to further clarify that the identification of a critical event or issue is intended to be a collaborative one.

Several commenters suggested that the provisions that were developed by the ''conferring policy'' workgroup established in 2010 be incorporated into the Policy. While, IHS is not required to adopt any recommendations of a workgroup or committee, it was determined that the ''conferring policy'' workgroup was convened in a manner that may not have complied with the requirements of the FACA. Therefore, although IHS considered the workgroup's discussion and recommendation to the same extent it considered all other recommendations received on this issue, federal staff developed a draft policy based on the statute and all comments received to that point, and published the draft in the **Federal Register** for comment. Many of the points raised in the discussion of the workgroup actually are consistent with the draft policy and were raised and responded to in the comments that were subsequently received. Some issues raised by the workgroup, but not included in the final policy, may require further conferring with UIOs.

One commenter expressed concern regarding violation of trust responsibility. The IHCIA defines ''confer'' to mean ''to engage in an open and free exchange of information and opinions that—(1) leads to mutual understanding and comprehension; and (2) emphasizes trust, respect, and shared responsibility.'' 25 U.S.C. § 1660d(a). IHS believes this will be accomplished through the various confer mechanisms that will be conducted in response to a critical event or issue.

A few commenters suggested that it was the intent of the IHCIA that the IHS confers only with UIOs funded by the IHS under the IHCIA. Similarly, another commenter suggested the definition of a UIO be inclusive to ensure adequate input and participation from the nonprofit organizations providing services to Tribal members living away from the reservation. The Policy is inclusive of all UIOs that meet the IHCIA definition of UIO, 25 U.S.C. 1603(29), which is not limited, per the statute, to organizations that are receiving funding from the IHS under the IHCIA. In practice, UIOs funded by the IHS under the IHCIA will have opportunities to raise issues specific to their relationship with IHS during the confer process and can also continue to approach IHS directly regarding such specific concerns, without relying on the conferring process set out in this policy.

Two commenters urged the IHS to consider coordination with the IHS Tribal Consultation Policy and Executive Order 13175. The commenters suggested that UIO matters could have Tribal implications that may trigger consultation and, therefore, Tribal governments should be included as a required party in the confer process with UIOs. The Policy published in this **Federal Register** notice addresses IHS's responsibility to confer with UIOs under the IHCIA. The IHS Urban Confer Policy does not change the Tribal Consultation Policy. IHS will continue to follow the Tribal Consultation Policy for consulting Indian Tribes on matters that will significantly affect Tribes. For issues of interest to both Tribes and UIOs, both policies will apply.

Final Policy, With Revisions Incorporated in Response to Above Comments

Policy on Conferring With Urban Indian Organizations

5–26.1 *Introduction*

A. *Purpose.* Congress has specifically declared that it is the policy of the Nation ''to ensure the highest possible health status for Indians and urban Indians.'' 25 United States Code (U.S.C.) § 1602(1). The U. S. Department of Health and Human Services (HHS) is committed to working with Indian and urban Indian communities to meet this policy. This policy applies to the Indian Health Service (IHS).

This Policy establishes the Indian Health Service (IHS) policy and procedures for conferring with urban Indian organizations (UIOs). The IHS will use this conferring Policy to ensure that the health care needs of the urban

Indian population are considered at the local, Area, and national levels, when implementing and carrying out the Indian Health Care Improvement Act (IHCIA or Act).

B. *Background.* Urban Indian organizations are a major provider of health care to urban AI/ANs across the country. When the IHCIA was enacted into law in 1976, it identified the authorities, responsibilities, and functions of the IHS, the primary Federal Agency charged with providing health care to American Indians and Alaska Natives (AI/AN). The IHCIA included the authority for the IHS to ''establish programs in urban centers to make health services more accessible to urban Indians'' [Indian Health Care Improvement Act, Title V, section 501, Public Law No. (Pub. L. No.) 94–437, 90 Statute (Stat.) 1400, 1410 (1976), codified at 25 U.S.C. § 1651]. The IHS carries out this authority through contracts with and grants to UIOs. In March 2010, as part of the Affordable Care Act, Congress reauthorized and amended the IHCIA. The reauthorization of the IHCIA included a requirement that the IHS ''confer,'' to the maximum extent practicable, with UIOs in carrying out the IHCIA.

C. *Policy.* It is IHS policy to confer with UIOs, to the maximum extent practicable, whenever a critical event or issue, as defined in this Policy, arises in implementing or carrying out the IHCIA.

D. *Requirement.* The IHCIA, as amended, includes four provisions that require the IHS to confer with UIOs.

(1) Indian Health Care Improvement Act, 25 U.S.C. § 1660d(b). ''The Secretary shall ensure that the Service confers, to the maximum extent practicable, with urban Indian organizations in carrying out this [Act].''

(2) Indian Health Care Improvement Act, 25 U.S.C. § 1602(5). ''Congress declares . . . that all actions under this [Act] shall be carried out with . . . conference with urban Indian organizations, to implement this [Act]. . . .''

(3) Indian Health Care Improvement Act, 25 U.S.C. § 1631(f). ''The Secretary shall . . . confer with urban Indian organizations, in developing innovative approaches to address all or part of the total unmet need for construction of health facilities. . . .''

(4) Indian Health Care Improvement Act, 25 U.S.C. § 1665k(a)(2)(A)(vii). ''Funding provided pursuant to [25 U.S.C. § 1665k ''fetal alcohol spectrum disorders programs''] shall be used . . . [t]o develop and implement . . . in conference with urban Indian organizations, culturally sensitive assessment and diagnostic tools including dysmorphology clinics and multidisciplinary fetal alcohol spectrum disorders clinics for use in Indian communities and urban centers.''

E. *Authorities.*

(1) Indian Health Care Improvement Act, 25 U.S.C. §§ 1601–1683, as amended, including, §§ 1602(1), 1603(29), 1651, 1653(a), 1660d.

F. *Definitions.*

(1) *Confer.* The term ''confer'' means to engage in an open and free exchange of information and opinions that:

a. Leads to mutual understanding and comprehension, and

b. emphasizes trust, respect, and shared responsibility. 25 U.S.C. § 1660d(a).

(2) *Conferring Activities.* The term ''conferring activities'' means implementing confer mechanisms, such as face-to-face meetings, teleconferences, and mailings, to solicit comments and discuss critical events or issues.

(3) *Critical Event or Issue.* A ''critical event or issue,'' as used in this Policy, is an event or issue that significantly affects one or more UIOs. Critical events or issues are complex, have significant implications, and are time sensitive. Examples of critical events or issues include developing program regulations, formulating the budget, allocating new resources, and changing policy, as well as public health or environmental events.

(4) *IHS Confer with UIOs Report.* The term ''IHS Confer with UIOs Report'' means an annual report to the Secretary, HHS, describing critical events or issues to UIOs arising in implementing or carrying out the IHCIA.

(5) *Urban Indian Organization.* The term ''urban Indian organization'' means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in [25 U.S.C. 1653(a)]. 25 U.S.C. 1603(29).

5–26.2 Objectives

A. To formalize the IHS approach to conferring with UIOs to ensure that urban Indian health priorities and goals are considered.

B. To establish a minimum set of requirements and expectations with respect to conferring for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

C. To identify critical events or issues arising in implementing or carrying out the IHCIA for which conferring with UIOs will be required for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

D. To identify critical events or issues arising in implementing or carrying out the IHCIA where partnerships and the inclusion of UIOs would complement consultation with Indian Tribes.

E. To require conferring with UIOs on proposed, new, and existing health policies and programs that qualify as critical events or issues arising in implementing or carrying out the IHCIA.

F. To promote and develop innovative methods of involving UIOs in IHS policy development and in the decision-making processes of the IHS.

G. To charge and hold responsible all levels of management within the IHS for the implementation of this Policy.

5–26.3 Roles

A. *Headquarters.* The Director, IHS, is responsible for providing overall guidance and direction to the Office of Urban Indian Health Programs (OUIHP) and ensuring that the IHS confers, to the maximum extent practicable, with UIOs in accordance with this Policy.

The IHS has the responsibility to engage in an open and free exchange of information and opinions with UIOs that leads to mutual understanding and comprehension; and emphasizes trust, respect, and shared responsibility whenever a critical event or issue, as defined in this Policy, arises in implementing or carrying out the IHCIA.

The Director, OUIHP, is responsible for monitoring compliance with this Policy, including submissions to the OUIHP conferring email address: *urbanconfer@ihs.gov.* The Director, OUIHP, will ensure that all levels of the IHS conduct official conferring sessions that are publicized through correspondence or, when necessary, **Federal Register** Notices (FRN) and receive conferring reports. The Director, OUIHP, will also receive and acknowledge receipt of written correspondence from UIOs identifying critical events or issues arising in implementing or carrying out the IHCIA. Such correspondence should identify the critical events or issue, the affected UIO(s), and the proposed conferring activity. After receiving such correspondence, or upon identification of a critical event or issue by IHS, all affected UIOs will be notified through a ''Dear Urban Indian Organization Letter'' and broadcast emails, and, if necessary, through the **Federal Register**, when IHS will undertake conferring activity. The notice will identify the issue, the method for conferring, and the

timeline for the conferring activity. The Director, OUIHP, is responsible for preparing the annual IHS Confer with Urban Indian Organizations Report.

All IHS Headquarters Office Directors will provide leadership to identify potential critical events or issues arising in implementing or carrying out the IHCIA for which conferring with UIOs will be recommended to the Director, OUIHP, and assist the OUIHP in completion of the annual IHS Confer with UIOs Report, when necessary.

B. *Area Offices.* The Area Director will provide the support and assistance to ensure that IHS confers, in accordance with this Policy, with UIOs at the Area level. The Area Director will conduct official conferring sessions through meetings or conferring actions with UIOs. The Area Director will ensure that the Director, OUIHP is informed of the Area conferring activities and outcomes for inclusion in the annual IHS Confer with UIOs Report.

C. *Service Units.* The Service Unit Chief Executive Officer (CEO) is responsible for ensuring compliance with this Policy by conferring with UIOs that are located in the Service Unit, if applicable. The CEO shall provide the Service Unit conferring activities and results or outcomes reports to the Area Director, who will report them to the OUIHP.

5–26.4 Confer Management

A. *Identification of Conferring Activities.* A potential critical event or issue arising in implementing or carrying out the IHCIA may be identified by either the IHS and/or UIOs.

(1) If a potential critical event or issue is identified by a UIO, written correspondence must be submitted to the Director, IHS, (with a copy to the appropriate Area Director) describing the event or issue, the affected UIO(s), and the proposed conferring activity. The IHS shall acknowledge receipt of the request within 60 business days.

(2) Within 60 business days of acknowledging the request, IHS shall provide an official response to all affected/potentially affected UIO(s), identifying the conferring activity that has been selected and the timeline for the activity. In addition, if IHS itself determines that a critical event or issue has arisen in implementing or carrying out the IHCIA, the IHS will issue notices to all affected/potentially affected UIOs through correspondence such as a ''Dear Urban Indian Organization Letter'' and broadcast emails, as well as through a FRN, if necessary. The communication will identify the critical events or issues to be discussed, as well as the mechanism for conferring.

B. *Conferring Activity.* The IHS will conduct official conferring activities that shall be publicized, both through correspondence such as a ''Dear Urban Indian Organization Letter'' and broadcast emails, and, if necessary, through a FRN. The notices will include information such as the mechanism, dates, and locations of the conferring activity, the agenda, and any critical events or issues that will be discussed. In the event that a confer activity will be conducted, the degree and extent of the conferring and the mechanism for conferring shall depend upon several factors, including:

(1) The nature of the critical event or issue,

(2) the number of potentially affected UIOs, and

(3) the most cost effective and efficient conferring mechanism, based on the nature of the critical event or issue and the number of potentially affected UIOs.

C. *Confer Mechanisms.* The IHS will consider the following confer mechanisms as options that provide the opportunity for an open and free exchange of information and opinions that lead to mutual understanding and comprehension and emphasize trust, respect, and shared responsibility:

(1) Mailings

(2) Teleconferences/Webinars

(3) Regular or special program level conferring sessions

(4) Conferences or meetings, such as the annual Urban Indian Health Leadership Conference

(5) Opportunities for comment, including submissions to *urbanconfer@ihs.gov*

(6) Face-to-face meetings, including meetings conducted at the Area Office level or at the national-level Indian health system meetings that include the IHS, Tribes, and UIO(s).

(7) **Federal Register** Notices with request for comment.

D. *Contract- and Grant-Specific Issues.* A UIO may request to meet one-on-one with an IHS representative to confer on issues specific to that UIO and its contract and grant awards from the IHS.

E. *Unresolved Issues.* Upon the completion of any of the conferring activities in this section, the IHS will document and follow-up on any unresolved issue(s) that would benefit from the ongoing involvement of the affected UIO(s). Documentation of the conferring process and outcomes will be maintained by the OUIHP and the Area Office(s) in which the affected UIO(s) are located.

F. *Annual IHS Confer With UIOs Report to HHS.* The IHS shall prepare and submit the annual IHS Confer with UIOs Report to the Secretary, HHS, describing critical events or issues arising in implementing or carrying out the IHCIA, related conferring activities, and the results and outcomes of conferring with UIOs.

The report shall include a description of each critical event or issue(s) that was the subject of conferring, a description of the process that was used, a discussion of the recommendations that resulted from the conferring activity, a list of any follow-up action items, a timeline for addressing these items, and a discussion of the level of satisfaction with the conferring process.

G. *Conflict Resolution.*

(1) The intent of this Policy is to promote mutual understanding and comprehension, and to emphasize trust, respect, and shared responsibility between the IHS and UIOs.

(2) However, the IHS and UIOs may not always agree. Where such disagreement occurs, nothing in this Policy creates a right of action against the IHS or the HHS for failure to comply with this Policy.

5–26.5 Federal Advisory Committee Act

The Federal Advisory Committee Act (FACA), 5 U.S.C. App. § 1–16, may apply to conferring activities. The FACA is implicated when an Agency establishes, manages, or controls a group that includes one or more participants who are not Federal employees for the purpose of obtaining the group's consensus advice or recommendations on Agency issues or policies. The FACA imposes several procedural requirements on Federal Agencies that convene advisory committees. Although FACA may not apply to groups consisting solely of Tribal leaders serving on the group in their official capacities, UIOs do not meet the requirements of the ''inter-governmental'' exemption. Accordingly, any conferring activities that qualify as an advisory committee under the FACA that is convened for the purpose of developing consensus recommendations will be required to comply with the procedures set out in FACA. For questions regarding the applicability of FACA, please contact the Director, IHS Division of Regulatory Affairs, Office of Management Services.

5–26.6 Summary

This policy considers a wide range of needs and unique characteristics in crafting these guidelines; therefore, it is important for the IHS urban confer

policy to remain dynamic and be responsive to changing circumstances that affect UIOs. It is expected that the confer process may result in the need to update the policy from time to time.

5–26.7 Deliberative Process Privilege

Nothing in this Policy waives the Government's deliberative process privilege. Examples of the government's deliberative process privilege are as follows:

(1) When the Secretary, HHS, is specifically requested by a member or members of Congress to respond to or report on proposed legislation, the development of such responses and of related policy is a part of the Executive Branch's deliberative process privilege and should remain confidential.

(2) In specified instances, when Congress requires the HHS to work with UIOs on the development of recommendations that may require legislation, such as reports, recommendations, or other products that are developed independent of a Department position, the development of which is governed by Office of Management and Budget Circular A–19.

Dated: September 22, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014–23005 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; A Generic Submission for Formative Research, Pre-Testing, Stakeholder Measures and Advocate Forms at NCI

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 18, 2014 (Volume 79, P. 42023) and allowed 60-days for public comment. There were no comments received.

Direct comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Kelley Landy, Acting Director of the Office of Advocacy Relations (OAR), NCI, NIH, 31 Center Drive, Bldg. 31, Room 10A28, MSC 2580, Bethesda, MD 20892, call non-toll-free number 301–594–3194, or email your request, including your address, to *kelley.landy@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI, 0925–0641, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and feedback, and facilitates collaboration to advance NCI's authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Pre-testing, or formative evaluation, helps ensure that the products and services developed by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. The OAR will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this research, allowing NCI to: 1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective strategies, concepts, activities; 2) use a feedback loop to help refine, revise, and enhance OAR's efforts—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and 3) expend limited program resource dollars wisely and effectively. The anticipated individual respondents will consist of: Adult cancer research advocates, members of the public, health care professionals, and organizational representatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,025.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent type	Form name	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Individuals	Self-Administered Questionnaires	800	1	1	800
	Individual In-Depth Interviews	75	1	1	75
	Focus Group Interviews	100	1	90/60	150