''outcomes'' and ''outputs'' if I don't know what they mean to you? Or are they the same meaning to you and it's just a change in the words that are going to be used?

Response: ANA's intent is to provide more universally accepted terminology, especially for evaluation requirements and criteria. Definitions and examples of all new terms will be provided in each of the FY 2018 FOAs. Any new terminology will be addressed in Section I. Program Description of the FOA. ANA will explain each term and include examples of each. Definitions will be included in the appendix of each FOA.

B. ANA Administrative Policy Regarding Prioritized Funding for Local, Community-Based, Native American Organizations as Described in the August 14, 2017, NOPC (82 FR 37861)

ANA has edited the description of this policy since it was published in the **Federal Register**, to further clarify the requirements for non-local, national, and regional organizations. If approved, ANA intends to include this policy in all FY 2018 FOAs as stated below:

Prioritized Funding for Community-based Native American Organizations:

ANA reserves the right to prioritize funding to community-based Native American organizations serving their local communities and populations. Applications from non-local, national, and regional organizations that propose projects to serve multiple communities, or to be performed in a different geographic location, must clearly demonstrate that the need for the project was originated by the each community being served, and that the community and/or tribal government supports the proposed project. They must also describe how each community was selected, identify and describe the intended beneficiaries, demonstrate community involvement in the development of the project, and discuss a community-based delivery strategy for the project. The proposed project goals, objectives, and outcomes must address goals of the community being served. National and regional organizations must describe their membership, and define how the organization operates. The type of community to be served will determine the type of documentation necessary to support the project.

C. Additional Information Regarding Project Start Dates for Language Preservation and Maintenance, and Native Language Esther Martinez Immersion Grants

Through continued discussions with ANA grantees and stakeholders, ANA has determined that moving the start date from August 1 to July 1 for projects funded under the Native Language Preservation and Maintenance and the Native Language Esther Martinez Immersion programs will align reporting requirements to reduce the number of required federal financial reports, thereby reducing the reporting burden for grantees. In addition, an earlier start date will provide projects with additional time for planning and start up prior to the start of the school year, which marks the beginning of instruction for many Native Language projects. Therefore, ANA intends to implement a July 1 start date for all projects funded under the Native Language Preservation and Maintenance and Native Language Esther Martinez Immersion FOAs for FY 2018.

D. Application Period Notification

ANA would like to notify potential applicants that the open application period to respond to FOAs has been updated to a minimum of 60 days to support the timely award of new grants.

E. Funding Opportunity Announcements

For information on the types of projects funded by ANA, please refer to ANA's Web site for information on our program areas and FOAs: *https://www.acf.hhs.gov/programs/ana.* Pre-publication information on ANA's FOAs will be available at *https://www.grants.gov/web/grants/search-grants.html* by clicking on 'Forecasted'' under Opportunity Status and ''Administration for Children and Families—ANA [HHS–ACF–ANA]'' on the left side of the page. Synopses and application forms will be available on *www.Grants.gov*.

Stacey Ecoffey,

Acting Commissioner, Administration for Native American, ACF, Acting Deputy Assistant Secretary for Native American Affairs, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0221]

Formal Dispute Resolution: Sponsor Appeals Above the Division Level; Guidance for Industry and Review Staff; 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 guidance for industry and review staff entitled ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level.'' This guidance provides recommendations for industry and review staff on the procedures in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and/or medical disputes between CDER or CBER and sponsors that cannot be resolved at the division level. This guidance describes the formal dispute resolution procedures for sponsors that wish to appeal a scientific and/or medical issue to the office or center level and provides a structured process for resolving disputes. This guidance finalizes the revised draft guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level'' issued September 9, 2015, and replaces the guidance of the same name issued February 2000.

DATES: The announcement of the guidance is published in the **Federal Register** on November 6, 2017.

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–2013–D–0221 for ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level; Guidance for Industry and Review Staff; Availability.'' 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.

• 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.

You may submit comments on any guidance at any time (see 21 CDR 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, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Khushboo Sharma, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6486, Silver Spring, MD 20993–0002, 301–796–0700; or, 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and review staff entitled ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level.'' During the course of review of an investigational new drug application, new drug application, biologics license application, or abbreviated new drug application, a wide variety of important scientific and/or medical issues are considered that are central to product development. Sometimes, a sponsor may disagree with the Agency on a matter, and a dispute arises. Because these disputes often involve complex scientific and/or medical matters, it is critical to have procedures in place to help ensure open and prompt discussion. The procedures and policies described in this guidance are intended to promote rapid and fair resolution of scientific and/or medical disputes between a sponsor and CDER or CBER.

This guidance finalizes the revised draft guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level'' issued September 9, 2015, and replaces the guidance of the same name issued February 2000. Based on the docket comments for the revised draft guidance, FDA made clarifications to this guidance. The guidance was also clarified to reflect that it describes the formal dispute resolution procedures only for sponsors that wish to appeal a scientific and/or medical issue regarding their applications regulated by CDER or CBER and does not apply to other individuals or entities. In addition, the guidance was updated to reflect the changes under the 2017 reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA) regarding timelines for reviewing disputes involving drug applications covered by GDUFA.

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 formal dispute resolution requests for appeals above the division level. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0430. This guidance finalizes a revision of an earlier version of the guidance. This version contains no additional information collections; therefore, it continues to be covered under OMB control number 0910–0430.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidancecompliance regulatoryinformation/guidances/default.htm, https://www.fda.gov/biologicsbloodvaccines/guidancecompliance regulatoryinformation/default.htm,* or *https://www.regulations.gov.*

Dated: October 31, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24096 Filed 11–3–17; 8:45 am]

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