

State (DOS) or the U.S. Department of Homeland Security (DHS).
Participating voluntary agencies agree to match the ORR grant with cash and

in-kind contributions of goods and services from the community. Currently, ORR awards \$2 for every \$1 raised by

the agency up to a maximum of \$2,200 in federal funds per client.
Single-source awards are made to the following organizations:

| Grantee name | Location | Total federal annual award |
|--|----------------|----------------------------|
| Church World Service/Immigration & Refugee Program | New York, NY | \$5,885,000 |
| Domestic and Foreign Missionary Society of the Protestant Episcopal Church of the U.S.A | New York, NY | 4,241,600 |
| Ethiopian Community Development Council/Refugee Resettlement Program | Arlington, VA | 2,059,200 |
| HIAS, Inc. (Hebrew Immigrant Aid Society)/Refugee and Immigrant Services | New York, NY | 1,566,400 |
| International Rescue Committee/Resettlement | New York, NY | 9,143,200 |
| Lutheran Immigration & Refugee Service | Baltimore, MD | 7,530,600 |
| United States Conference of Catholic Bishops | Washington, DC | 18,977,200 |
| US Committee for Refugees and Immigrants | Arlington, VA | 11,501,600 |
| World Relief Corporation of National Association of Evangelicals/Refugee & Immigration Programs. | Baltimore, MD | 4,404,400 |

Statutory Authority: Section 412(c)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1522(c)(1)(A)); Section 7(a) and (b) of the Refugee Assistance Extension Act of 1986 (Pub. L. 99-605) (8 U.S.C. 1522 note).

Christopher Beach,
Senior Grants Policy Specialist, Office of Administration.

[FR Doc. 2015-01841 Filed 1-30-15; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Termination of the Commonwealth of Puerto Rico's Protection and Advocacy for Persons With Developmental Disabilities Award

AGENCY: Administration for Community Living, HHS.

ACTION: *Notice of Hearing:* Termination of PADD funding. Action to Terminate the Commonwealth of Puerto Rico's Protection and Advocacy for Persons with Developmental Disabilities (PADD) Award.

SUMMARY: Pursuant to regulations at 45 CFR part 1386, subpart D, this notice announces an administrative hearing regarding termination of Federal funding (that is, "the allotment") for the Protection and Advocacy for Persons with Developmental Disabilities (PADD) Award to the designated Protection and Advocacy agency in the Commonwealth of Puerto Rico: Oficina del Procurador de las Personas con Impedimentos (OPPI) (Ombudsman for Persons with Disabilities). This notice includes the following information: Who will preside at the hearing, the organizations or entities that are parties to the hearing without making a specific request to participate, the due dates for those who

are not parties as of right to file a petition to participate as a party or as an amicus curiae, the date and place of the hearing, how certain procedural provisions in the applicable regulations have been modified, and a description of the issues to be considered at the hearing.

FOR FURTHER INFORMATION CONTACT: Carolyn Reines-Graubard, Director, Appellate Division, Departmental Appeals Board, Cohen Building, Rm. G-644, MS 6127, 330 Independence Ave. SW., Washington, DC 20201, 202-565-0116.

Background: The Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) (codified at 42 U.S.C. 15001 *et seq.*) provides states and territories with federal money for the purpose of assuring that "individuals with developmental disabilities and their families participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life, through culturally competent programs authorized" by the Act. DD Act § 101(b) (42 U.S.C. 15001(b)). While a number of programs are authorized under the DD Act, the relevant program for this proceeding is the Protection and Advocacy (P&A) system, described in Subtitle C of Title I of the DD Act and, relatedly, the State Council on Developmental Disabilities (SCDD), described in Subtitle B of such Title.

P&A systems are to "protect the legal and human rights of individuals with developmental disabilities." DD Act § 101(b)(2) (42 U.S.C. 15001(b)(2)). State Councils are to engage in "advocacy, capacity building, and systemic change activities that are consistent with the

purpose and policies of the Act," DD Act § 101(b)(1)(A) (42 U.S.C. 15001(b)(1)(A)), and that "contribute[] to a coordinated, consumer- and family-centered, consumer- and family-directed, comprehensive system that includes needed community services, individualized supports, and other forms of assistance that promote self-determination for individuals with developmental disabilities and their families." DD Act § 101(b)(1)(B) (42 U.S.C. 15001(b)(1)(B)). As a condition of funding the SCDD, the State must establish a P&A system to "to protect and advocate the rights of individuals with developmental disabilities." DD Act § 143(a)(1) (42 U.S.C. 15043(a)(1)).

Under the DD Act, a P&A system must have certain powers. Such powers include, but are not limited to, the authority to "pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of such individuals within the State who are or who may be eligible for treatment, services, or habilitation, or who are being considered for a change in living arrangements, with particular attention to members of ethnic and racial minority groups," as well as to "investigate incidents of abuse and neglect . . . if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred." DD Act § 143(a)(2)(A)(i) and (B) (42 U.S.C. 15043(a)(2)(A)(i) and (B)).

Pertinent regulations implementing the DD Act are contained in 45 CFR parts 1385 and 1386. Part 1385 includes general requirements applicable to most programs and projects authorized under the DD Act, including both the SCDDs and P&A systems. Part 1386 is specific to SCDDs and P&A systems. Subpart A of Part 1386 contains regulations applicable to both programs; Subpart B

is specific to P&A systems; Subpart C is specific to SCDDs, and Subpart D contains the practices and procedures for administrative hearings, such as the hearing in this proceeding.

Designation of Presiding Officer: Section 1386.100(a) of 45 CFR states that the “presiding officer at a hearing must be the Assistant Secretary”—defined in section 1386.80 as the Assistant Secretary for Children and Families—“or someone designated by the Assistant Secretary.” In 2013, the Assistant Secretary for Children and Families delegated his authorities under the DD Act to the Administrator, Administration for Community Living (ACL). 78 FR 16510 (Mar. 15, 2013). The Administrator, ACL, has designated Leslie A. Sussan, a member of the Departmental Appeals Board (DAB), as the Presiding Officer at the hearing. The Presiding Officer will certify the entire record, including recommended findings and a proposed decision, to the Administrator, ACL, who will issue a decision in accordance with 45 CFR 1386.111.

Requests for Participation: Pursuant to 45 CFR 1386.94(a), the Administration for Intellectual and Developmental Disabilities (AIDD) within ACL; OPPI; the Puerto Rico Developmental Disabilities Council (PRDDC); and the Office of the Governor, on behalf of the Commonwealth of Puerto Rico, are parties to the hearing without making a specific request to participate. Any individual or group not a party as of right under section 1386.94(a) that wishes to participate as a party must file a petition containing the information required by section 1386.94(b)(2)(i)–(iv) with the Presiding Officer no later than 15 days after the date of publication of this notice in the **Federal Register**.

Any interested person or organization that wishes to participate as an amicus curiae must file a petition that contains the information required by section 1386.94(c)(1)(i)–(iii). The petition must also state whether the interested person or organization will submit a written statement of position prior to the hearing and whether it wishes to present a brief oral statement at the hearing and/or to submit a brief or written statement at such time as the parties submit briefs. The petition must be filed with the Presiding Officer at least 15 days before the scheduled hearing date below in order to facilitate hearing arrangements.

If the deadline for filing a petition falls on a federal non-workday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a non-workday for

federal employees), the submission may be filed on the next federal workday.

Effect of a Final Determination: The decision of the Presiding Officer will be reviewed by the Administrator of ACL, in accordance with 45 CFR 1386.111. If the Administrator reaches a final determination that OPPI does not comply with Federal requirements, and determines that Federal funding (*i.e.*, allotments) will not be made pursuant to such decision, thus terminating the PADD grant, such decision will also terminate funding for the Commonwealth’s SCDD in addition to the P&A. Pursuant to section 143(a) of the DD Act (42 U.S.C. 15043(a)), as well as 45 CFR 1386.21(a), in order for a State to receive an allotment for its SCDD, the State must have in effect a P&A system meeting Federal requirements.

Other HHS programs providing grants to P&A organizations incorporate the DD Act. These programs are:

(a) The Protection and Advocacy for Individuals with Mental Illness (PAIMI) program. Specifically, 42 U.S.C. 10802(2) defines an eligible system as a system “established in a State to protect and advocate the rights of persons with developmental disabilities under subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000.”

(b) The Protection and Advocacy for Voting Access (PAVA) program under the Help America Vote Act of 2002. Specifically, 42 U.S.C. 15461(a) states that the Secretary of Health and Human Services “shall pay the protection and advocacy system (as defined in section 15002 of this title) of each state”

(c) The Protection and Advocacy for Traumatic Brain Injury (PATBI) program. Specifically, 42 U.S.C. 300d–53(m) defines a “protection and advocacy system” as a “protection and advocacy system established under part C of the Developmental Disabilities Assistance and Bill of Rights Act. . . .”

Such programs either require the existence of a P&A under the DD Act or define the P&A with reference to such Act. Therefore, a final decision that the Commonwealth of Puerto Rico does not have a system in effect to protect and advocate the rights of individuals with developmental disabilities because OPPI does not meet the statutory and regulatory requirements to serve as a P&A may also result in suspension or termination of grant funding under these programs based on ineligibility.

Federal programs outside HHS (such as the Protection and Advocacy for Individual Rights (PAIR) program under section 509 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794e)) also

refer to the DD Act. However, this Notice does not address the effect of a final decision in this case on those programs.

Date, Time and Place Of Hearing: Pursuant to 45 CFR 1386.84, the Administrator, ACL, modifies the requirements for the notice of hearing in section 1386.90 as follows, having determined that this modification will serve justice and will not unduly prejudice any party.

Rather than setting an exact time and a specific calendar date for the hearing, this Notice announces that the hearing will commence 45 days from the date this notice is published in the **Federal Register** (or the first federal workday thereafter, if the 45th day falls on a federal non-workday) at a time to be determined by the Presiding Officer. If the Presiding Officer reschedules the hearing pursuant to 45 CFR 1386.101(a)(1), the Presiding Officer will notify all parties and amicus curiae.

The hearing is expected to be conducted using videoconference. A non-federal party (including a non-federal party under section 1396.94(a)) that believes an in-person hearing is necessary because it is incapable of reasonably presenting its case by videoconference must submit a statement to that effect with supporting reasons no later than the date specified above for filing a petition to participate as a party. If the Presiding Officer determines that an in-person hearing is warranted, the Presiding Officer will notify the parties of the hearing location after consulting with the parties. Otherwise, the Departmental Appeals Board will arrange for appropriate videoconference facilities for the non-federal parties in Puerto Rico. Because it is based in Washington, DC, AIDD will participate in person, rather than by videoconference. A party may also request that an individual witness’s testimony be taken by telephone if it is not feasible for the witness to appear by videoconference or in person.

The Presiding Officer will schedule a pre-hearing conference after ruling on any petitions to participate as a party pursuant to section 1386.94(b)(2). The pre-hearing conference will be held by teleconference or by videoconference.

Filing and Service Requirements: Pursuant to 45 CFR 1386.84, the Administrator, ACL, modifies the requirements for filing and service of papers in section 1386.85 as follows, having determined that this modification will serve justice and will not unduly prejudice any party.

Parties as of right under section 1386.94(a) are required to use the Departmental Appeals Board’s

electronic filing system (DAB E-File) for all submissions. Instructions for using DAB E-File are at https://dab.efile.hhs.gov/appeals/Board/Appellate_Div_instructions. Any other party, as well as any amicus curiae, must file its petition to participate by paper and must use DAB E-File for all submissions that are filed after its petition to participate has been granted unless the party or amicus files with its petition an explanation of why it is unable to file submissions electronically and the Presiding Officer permits the party or amicus to file paper submissions.

A submission will be deemed to have been filed with the Presiding Officer on a given day if it is uploaded to DAB E-File on or before 11:59 p.m. eastern time of that day. A submission filed by paper will be deemed to have been filed with the Presiding Officer on the postmark date, the date sent by registered or certified mail, or the date deposited with a commercial delivery service. A party using DAB E-File must serve a paper copy of its submissions on any party or amicus curiae permitted by the Presiding Officer to file submissions by paper.

All submissions should be addressed to Leslie A. Sussan, Presiding Officer. The mailing address for paper submissions to the Presiding Officer is Departmental Appeals Board, Appellate Division, Cohen Building, Room G-644, MS6127, 330 Independence Ave. SW., Washington, DC 20201.

In order to facilitate compliance with section 1386.82 (providing that all documents filed are subject to public inspection), parties and amici curiae should redact all briefs, exhibits, and other written submissions in order to avoid the disclosure of any personally identifiable information (PII) and other information the disclosure of which might violate the Health Insurance Portability and Accountability Act (HIPAA), the Privacy Act of 1974, or State or other privacy or confidentiality requirements.

Discovery Procedures: Pursuant to 45 CFR 1386.84, the Administrator, ACL, modifies the provisions for discovery in section 1386.103 as follows, having determined that this modification will serve justice and will not unduly prejudice any party, as it conforms to the discovery procedures already used in other HHS administrative proceedings.

AIDD and OPPI, as the parties named in the notice issued under 45 CFR 1386.90, have the right to conduct discovery, but the Presiding Officer will not necessarily follow the Federal Rules of Civil Procedure, which do not by their own terms apply to administrative

proceedings. Before filing a discovery motion, a party should seek voluntary production from the other party. Any motion should describe specifically the information sought and state how this information is relevant and necessary to the party's case. The Presiding Officer will order production of specific items of information if the Presiding Officer determines that the party needs that information to address a dispositive issue in the case. Neither interrogatories nor depositions will be permitted unless the Presiding Officer determines that these are the only means to adequately develop the record on a dispositive issue.

Issues To Be Considered at the Hearing: The issues to be considered at the hearing are:

- *Whether the Commonwealth of Puerto Rico has in effect a system to protect and advocate the rights of individuals with developmental disabilities that meets the definition in section 102 of the DD Act (42 U.S.C. 15002) and that complies with sections 143(a) and 144 of such Act (42 U.S.C. 15043(a) and 15044), as well as regulations at 45 CFR part 1386, subpart B.* It is the position of AIDD that OPPI has failed to demonstrate that OPPI, as the Commonwealth's designated P&A system, has sufficient operations, independence, staff, and expertise to exercise the authorities necessary and required under the DD Act to protect the legal and human rights of people with developmental disabilities. The following sub-issues are considered:

- *Whether OPPI exercises the authorities of the P&A as required by sections 143(a)(2)(A) and (B)¹ of the DD Act and 45 CFR 1386.21(a)&(c).* OPPI has failed to demonstrate that the P&A is pursuing legal, administrative, and other appropriate remedies or approaches, such as individual legal advocacy, individual case representation, and systemic litigation, to ensure the protection of, and advocacy for, the rights of individuals with developmental disabilities. OPPI documentation provides for an administrative hearing process, but not other litigation, legal action or advocacy that would ensure the protection and advocacy envisioned by the statute and regulations. 45 CFR 1386.21(c) states that a P&A system "shall not implement

a policy or practice restricting the remedies which may be sought on behalf of the individuals with developmental disabilities or compromising the authority of the . . . P&A . . . system to pursue such remedies through litigation, legal action or other forms of advocacy." Because OPPI has a policy for only one type of remedy (an administrative remedy) and does not have policies regarding other types of legal remedies, OPPI has not provided sufficient assurances or evidence that the P&A is not de facto restricted from pursuing appropriate legal remedies to ensure the protection of, and advocacy for, the rights of individuals with developmental disabilities. OPPI also has failed to demonstrate that the P&A is providing information and referral services consistent with the DD Act. OPPI has an information and referral form to document the nature of an individual's disability, but it has not provided any other document, policy or evidence for how it carries out information and referral consistent with the requirements in the DD Act. OPPI has failed to demonstrate that the P&A is conducting investigations of incidents of abuse and neglect of individuals with developmental disabilities.

- *Whether OPPI, as a government agency, exercises the authorities of the P&A as required by sections 143(a)(2)(A), (B) and (G) of the DD Act and 45 CFR 1386.21(a)&(c).* OPPI does not have sufficient independence from the Governor for the P&A to adequately pursue legal, administrative, and other appropriate remedies or approaches to ensure the protection of, and advocacy for, the rights of individuals with developmental disabilities. Specifically, OPPI lacks the financial, structural, and leadership independence necessary to adequately carry out the requirements of a P&A system. With respect to financial independence, OPPI is a government agency and subject to the budgeting priorities and processes of other government agencies. OPPI has repeatedly informed AIDD that it does not have access to PADD funds to hire new attorneys or to travel to receive training related to the PADD grant. With respect to structural independence, as a government agency, the P&A must follow certain requirements that interfere with its ability to carry out the functions of the DD Act, such as maintaining a minimum amount of administrative staff. Limits on financial and structural independence also result in OPPI not maintaining necessary staff. Currently, only two attorneys are employed by OPPI, and such attorneys

¹ Although 45 CFR 1386.21(a) cites to section 142 of the DD Act, section 143 of DD Act of 2000 superseded such section. Section 401 of the DD Act of 2000 (Pub. L. 106-402) repealed the prior version of the Developmental Disabilities Assistance and Bill of Rights Act, codified at 42 U.S.C. 6000 *et seq.* System requirements for the P&A previously included in section 142 of the Act are now included in section 143 of the Act (compare 42 U.S.C. 6042 (1999) with 42 U.S.C. 15043 (2014)).

serve at the pleasure of the Governor; as state-funded employees, they are at risk of losing their positions, thus implicating the ability to truly investigate and bring cases against State-run institutions. With respect to independent leadership, both the OPPI Ombudsman, who is the Executive Director of the P&A, and the Advisory Council are appointed by the Governor, and the Ombudsman can be removed by the Governor. As such, OPPI fails to operate free of influence from the Governor. Section 143(a)(2)(G) requires that the P&A be independent of any agency that provides treatment, services, or habilitation to individuals with developmental disabilities. Act 78, Article 6 requires that the Advisory Council have members representing service-providing entities making it unclear whether this supports P&A independence as required in the DD Act.

○ *Whether OPPI maintains sufficient numbers and types of staff (qualified by training and experience) to carry out the P&A system's functions, as required by section 143(a)(2)(K) of the DD Act and 45 CFR 1386.21(e), and is free from any State policies which prevent the P&A from carrying out its authorities and other mandates under the Act, including whether the P&A is exempt from hiring freezes, reductions in force, prohibitions on travel, or other policies to the staff of the system, to the extent that such policies would impact the staff or functions of the system funded with Federal funds or would prevent the system from carrying out the functions of the system, as required by section 143(a)(2)(K) of the DD Act and 45 CFR 1386.21(d).* OPPI has only two attorneys on its staff of more than 70 employees. Neither attorney is authorized to practice before the Federal courts in the Commonwealth. This is a barrier to the P&A being able to preserve and exercise its authority to pursue legal, administrative, and other appropriate remedies or approaches authorized under the DD act, as cases invoking the authority of a Federal statute would be brought in Federal court. Further, two attorneys is an insufficient number for a P&A to preserve and exercise its authority to pursue legal, administrative, and other appropriate remedies or approaches. The P&A has an administrative staff of over 50 people; however, it is unclear what role and activities this staff is performing related to the PADD grant. All P&A staff are subjected to state hiring practices, including hiring freezes, which prevents the P&A from obtaining appropriate staffing to carry out its mandates, and in

violation of the above-cited regulations (45 CFR 1386.21(d) and (e)). The P&A lost advocate positions under the re-organization plan implemented in 2012 and was not able to replace those positions. OPPI has repeatedly informed AIDD that it does not have access to PADD funds to hire new attorneys or to travel to receive training related to the PADD grant.

○ *Whether the individuals served by the P&A are individuals with developmental disabilities as defined in section 102(8) and whether the P&A takes action with regard to goals and priorities, developed through data driven strategic planning, for the system's activities as required by section 143(a)(1) and (a)(2)(C) and (D) of the DD Act and in keeping with 45 CFR 1386.21(c) and 45 CFR 1386.23.* OPPI has a form to determine eligibility for the PADD program; however, the 2012 AIDD Monitoring and Technical Assistance Review System (MTARS) report states that OPPI had a poor understanding of the difference between developmental disabilities and other disabilities and seemed unclear about which clients of the P&A qualify for PADD funding. Therefore, this form does not provide adequate assurances that the people served with PADD funding are people with developmental disabilities. Furthermore, this form does not include information about whether the individual's issues fall within the P&A's priorities. The 2012 MTARS report states: "OPPI receives all complaints that include people with disabilities, regardless of the relativity of the complaint. Based on the limited resources available, OPPI is unable to handle every meritorious complaint. Therefore, OPPI needs to clarify the organizational structure and framework, then redevelop and apply the Goals and Priorities to determine which cases they may take, and which to refer out." OPPI has not presented evidence that it has a statement of goals and priorities (SGP) unique to the PADD program or that anticipates priorities for selecting specific cases or determining an individual advocacy caseload, systemic advocacy work and training activities, and outcomes it wishes to accomplish. OPPI submitted a Fiscal Year 2014 SGP to AIDD. However, the AIDD review of the SGP found it to be inadequate, as it was not based on any public comment, as required under the DD Act, and its goals lacked the specificity necessary to provide meaningful direction for the use of PADD funds and PADD case selection. As a result, AIDD did not approve the SGP. OPPI took minimal action to correct the SGP by submitting

commentary on its goal setting process, but it did not change the goals, or provide record of public comment. AIDD determined OPPI's minimal action was not sufficient to address the deficiencies. Failure to have an adequate SGP in place to guide the P&A activities means that OPPI is likely failing to meet the necessary priorities and mandates of the DD Act.

○ *Whether the P&A exercises the authority to access all records and individuals with developmental disabilities as required by Section 143(a)(2)(H–J) of the DD Act and 45 CFR 1386.22.* The 2012 MTARS identified that OPPI has the authority to access and conduct on-site monitoring visits of any individual with a developmental disability in Puerto Rico where services are provided. However, OPPI staff is generally unaware of their authority to access residential facilities and community settings. Therefore OPPI did not exercise this authority. Without fully exercising the P&A access authority, OPPI cannot fulfill its statutory mandate to protect the legal and human rights of individuals with developmental disabilities, in accordance with the purposes of the DD Act (section 101(b)(2) of the DD Act). The P&A is limited in its ability to carry out the legal, administrative, and other appropriate remedies in accordance with sections 143(a)(1) and (a)(2)(A) of the DD Act, if it does not demonstrate that it accesses records and/or individuals in accordance with sections 143(a)(2)(H)–(J) and 45 CFR 1386.22.

○ *Whether the P&A meets the requirements in Section 144(a)(5) that the majority of the members of an advisory council shall be individuals with disabilities, including individuals with developmental disabilities who are eligible for, have received or are receiving services through the system; or parents, family members, guardians, advocates, or authorized representatives of such individuals.* Act 78, Article 6 requires that the Advisory Council have 9 members: 1 person with a disability; 1 parent of a person with a disability; 1 legal advisor with experience in the field of disability rights; 1 vocational rehabilitation professional; 1 special education professional; 1 healthcare professional; and 2 people committed to fulfilling the principles outlined in the law creating OPPI. This does not guarantee that the Advisory Council meets the majority requirements in the DD Act.

○ *Whether the P&A is conducting PADD activities since they have not utilized FY2014 funds.* The PADD grant to OPPI is classified as high risk with restrictions on the funds. Payment is

made to OPPI on a reimbursement basis. OPPI has not submitted a request for reimbursement under the FY 2014 PADD grant award leaving the entire amount of the award unspent. It is unclear, then, how OPPI is exercising the P&A authorities and conducting P&A activities without utilizing the federal financial assistance.

Dated: January 27, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-01857 Filed 1-30-15; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1497]

Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notification of public meeting and request for comments that appeared in the **Federal Register** of October 30, 2014. The notification requested comments on certain topics related to our guidance titled “Toxicological Principles for the Safety Assessment of Food Ingredients,” known less formally as the “Redbook”. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notification of public meeting and request for comments published October 30, 2014 (79 FR 64603). Submit either electronic or written comments by May 11, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA-2014-N-1497) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jeremiah Fasano, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1173, jeremiah.fasano@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 30, 2014 (79 FR 64603), we published a notification of public meeting and requested comments on certain topics related to the Redbook. The Redbook provides guidance to industry and other stakeholders (e.g., academia and other regulatory groups) regarding the information used by FDA’s Center for Food Safety and Applied Nutrition to evaluate the safety of food additives and color additives. The Redbook is intended to help interested parties understand FDA’s expectations regarding:

- Determining the human exposure that will occur from the use of the ingredient in foods;
- Determining which toxicity studies are appropriate;
- Designing, conducting, and reporting the results of toxicity studies; and
- Submitting the information to FDA as part of a safety assessment.

Comments on the Redbook will inform our future efforts on what should be included, changed, or even excluded from the updated Redbook. We are interested in expanding the scope of the

Redbook to emphasize the principles of safety and risk assessment that are shared across different regulatory contexts for foods and cosmetics, while still providing specific guidance for applying these principles in particular contexts such as the requirements for premarket safety submissions or for risk assessments conducted on foods and cosmetics already on the market.

We have received a request for a 90-day extension of the comment period for the notification of public meeting and request for comments. The request conveyed concern that the current 90-day comment period (which would otherwise expire on February 9, 2015) does not allow sufficient time to develop meaningful or thoughtful responses to the notification of public meeting and request for comments.

We have considered the request and are extending the comment period for 90 days, until May 10, 2015. We believe that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying further action on these important issues.

II. Request for 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: January 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-01858 Filed 1-30-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2031]

For Nominations on the Food Advisory Committee; Extension of Closing Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of closing date.

SUMMARY: The Food and Drug Administration (FDA) is extending the closing date for the notice that appeared