10406(c)(5) regarding non-disclosure of confidential of private information (section 10407(a)(2)(A)).

(9) Pursuant to Section 10406(c)(5), comply with the new FVPSA provisions regarding non-disclosure of confidential or private information. As such, the applicant will comply with additional requirements imposed by that section which include but are not limited to: (A) Grantees shall not disclose any personally identifying information collected in connection with services requested (including services utilized or denied), through grantee's funded activities or reveal personally identifying information without informed, written, reasonably time-limited consent by the person about whom information is sought, whether for the FVPSA funded activities or any other Federal or State program (additional consent requirements have been omitted *but see section 10406(c)(5)(B)(ii)(I)* for further requirements); (B) grantees may not release information compelled by statutory or court order unless adhering to the requirements of section 10406(c)(5)(C); (C) grantees may share non-personally identifying information in the aggregate for the purposes enunciated in section 10406(c)(5)(D)(i) as well as for other purposes found in section 10406(c)(5)(D)(ii) and (iii).

(10) As prescribed by section 10406(c)(2) of the FVPSA, the Tribe will use grant funds in a manner which avoids prohibited discrimination on the basis of age, disability, sex, race, color, national origin, or religion.

(11) Funds made available under the FVPSA will be used to supplement and not supplant other Federal, State and local public funds expended to provide services and activities that promote the objectives of the FVPSA (section 10406(c)(6)).

(12) Receipt of supportive services under the FVPSA will be voluntary. No condition will be applied for the receipt of emergency shelter (section 10408(d)(2)).

(13) The Tribe has a law or procedure to bar an abuser from a shared household or a household of the abused person, which may include eviction laws or procedures (section 10407(a)(2)(H)).

Tribally Designated Official

Tribe or Tribal Organization

Appendix B

LGBTQ (Also Known as ''Two-Spirited'') Accessibility Policy

As the Authorized Organizational Representative (AOR) signing this application on behalf of

[*Insert full, formal name of applicant organization*]

I hereby attest and certify that:

The needs of lesbian, gay, bisexual, transgender, and questioning (also known as ''Two-Spirited'') program participants are taken into consideration in applicant's program design. Applicant considered how its program will be inclusive of and non-stigmatizing toward such participants. If not already in place, awardee and, if applicable, sub-awardees must establish and publicize policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin. The submission of an application for this funding opportunity constitutes an assurance that applicants have or will put such policies in place within 12 months of the award. Awardees should ensure that all staff members are trained to prevent and respond to harassment or bullying in all forms during the award period. Programs should be prepared to monitor claims, address them seriously, and document their corrective action(s) so all participants are assured that programs are safe, inclusive, and non-stigmatizing by design and in operation. In addition, any sub-awardees or subcontractors:

- Have in place or will put into place within 12 months of the award policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin;
- Will enforce these policies;
- Will ensure that all staff will be trained during the award period on how to prevent and respond to harassment or bullying in all forms, and;
- Have or will have within 12 months of the award, a plan to monitor claims, address them seriously, and document their corrective action(s).

Insert Date of Signature:

Print Name and Title of the AOR:

Signature of AOR:

[End of full FOA]

Statutory Authority: The statutory authority for this program is 42 U.S.C. 10401, *et. seq.*

Mark Greenberg,

Acting Assistant Secretary, Administration for Children and Families.

[FR Doc. 2014–15331 Filed 6–30–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0258]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Regarded as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 31, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0016. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Form FDA 3503—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179 and 180 (OMB Control Number 0910–0016)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective. Food Additive Petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the

conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency's regulations specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Under section 201(s) of the FD&C Act (21 U.S.C.321(s)), a substance is generally regarded as safe (GRAS) if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The FD&C Act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). To implement the GRAS provisions of the FD&C Act, FDA has set forth procedures for the GRAS affirmation petition process in § 170.35(c)(1) of its regulations.

While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

Interested persons may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a Master File submitted in support of Petitions according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals. FDA estimates that the amount of time for respondents to complete Form FDA 3503 will continue to be 1 hour.

Description of Respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of April 16, 2014 (79 FR 21469) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section/FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
CAPs						
70.25, 71.1	2	1	2	1,337	2,674	$5,600
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	2,614	0
FAPs						
171.1	3	1	3	7,093	21,279	0
Form FDA 3503	6	1	6	1	6	0
Total					26,573	5,600

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience with the petition process. FDA is retaining its prior estimate of the number of petitions received because the average number of petitions received annually has varied little over the past 10 years. The figures for hours per response are based on estimates from experienced persons in the Agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR

70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of two color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to $5,600 (1 × $2,600 + 1 × $3,000 listing fees = $5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15384 Filed 6–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0202]

Over-the-Counter Drug Monograph System—Past, Present, and Future; Public Hearing; 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 public hearing, published in the **Federal Register** of February 24, 2014 (79 FR 10168), requesting comment on how to improve or alter the current Over-the-Counter (OTC) Monograph Process for reviewing nonprescription drugs marketed under the OTC Drug Review. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by July 31, 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: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903–0002, 301–796–3519, *mary.gross@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 24, 2014 (79 FR 10168), FDA announced a public hearing to obtain input on the OTC Drug Review (sometimes referred to as the OTC Monograph Process, OTC Monograph, or OTC Drug Review). As stated in the **Federal Register** notice, FDA has been assessing the OTC Monograph Process and, in particular, has been considering how effectively the monograph system is functioning in today's world, 40 years after its inception, from the scientific, policy, and process perspectives. In the February 24, 2014, notice of public hearing, FDA announced it was soliciting comments about whether and how to modernize the process for the future. The public hearing was held to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process. Interested persons were originally given until May 12, 2014, to comment on the OTC Monograph Process.

II. Request for Comments

On our own initiative, we are reopening the comment period to allow interested persons additional time to comment to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent 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**). You should annotate and organize your comments to identify the specific questions identified by the topic to which they refer (see 79 FR 10168 at 10171, section III). 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: June 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15375 Filed 6–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0833]

Office of the Commissioner; Request for Comments on the Food and Drug Administration Fiscal Year 2014–2018 Strategic Priorities Document; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comments on its draft Strategic Priorities Fiscal Year (FY) 2014–2018 document. FDA has identified these cross-cutting strategic priorities and core mission goals that will guide its efforts to achieve its public health mission. FDA is seeking public comment to help further refine these priorities and goals.

DATES: Submit either electronic or written comments by July 31, 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: Darian Tarver, Office of the