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 0910–0721. 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.

Animal Food Labeling; Declaration of Certifiable Color Additives—21 CFR 501.22(k) OMB Control Number 0910–0721—Extension

This information collection is associated with requirements under 21 CFR 501.22(k) in which animal food manufacturers must declare the presence of certified and noncertified color additives in their animal food products on the product label. The Agency issued this regulation in response to the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) to make animal food regulations consistent with the regulations regarding the declaration of color additives on human food labels and to provide animal owners with information on the colors used in animal food.

Respondents to this collection are manufacturers of pet food that contain color additives. Manufacturers of certain food or food ingredients do not have products that contain color additives requiring certification (*e.g.,* food for chickens, fish, and some other species, including some pet foods) and would thus be minimally affected by § 501.22(k)(1). However, since we cannot rule out the possibility that they may at some point use a color additive requiring certification, we have consolidated the burden estimates for §§ 501.22(k)(1) and 501.22(k)(2). Additionally, we believe that this burden is more accurately characterized as a third-party disclosure burden because FDA does not require routine submission of pet food labeling to the Agency.

In the **Federal Register** of April 1, 2015 (80 FR 17445), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section/Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or make of color additive; labeling of color additives not subject to certification.	3,120	0.83	2,587	.25 (15 minutes)	647

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Having become effective November 18, 2013, the Agency estimates that the burden associated with the labeling requirements under § 501.22(k) apply only to new product labels. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation.

Based on A.C. Nielsen Data, FDA estimates that the number of animal food product units subject to § 501.22(k) for which sales of the products are greater than zero is 25,874. Assuming that the flow of new products is 10 percent per year, then 2,587 new animal food products subject to § 501.22(k) will come on the market each year. FDA also estimates that there are about 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (k)(2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.83 new products per year (2,587 new products/3,120 firms is approximately 0.83 labels per firm).

The Agency expects that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based on our experience with reviewing pet food labeling, FDA estimates that firms would require less than 0.25 hour (15 minutes) per product to comply with the requirement to include the color additive information pursuant to § 501.22(k). The total burden of this activity is 647 hours (2,587 labels × 0.25 hour/label is approximately 647 hours).

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16022 Filed 6–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2126]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Campaign To Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on

the Evaluation of FDA's Multicultural Youth Tobacco Prevention Campaigns.

DATES: Submit either electronic or written comments on the collection of information by August 31, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of FDA's Campaign To Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults OMB Control Number—0910-New

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing public education campaigns to help prevent and reduce tobacco use among lesbian, gay, bisexual and transgender (LGBT) young adults and thereby reduce the public health burden of tobacco. Overall the campaigns will feature events; advertisements on television and radio and in print; digital communications including social media; and other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use, FDA requests OMB approval to collect information needed to evaluate FDA's campaign to reduce tobacco use among LGBT young adults. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to conduct two studies to evaluate the effectiveness of its LGBT young adult tobacco prevention campaign: (1) An outcome evaluation study to evaluate the effectiveness of its LGBT young adult tobacco prevention campaign, and (2) a media tracking questionnaire to assess awareness of and receptivity to campaign messages. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

- Outcome Evaluation Study

The outcome evaluation study begins with a baseline survey of LGBT young adults aged 18 to 24 before the campaign launch. The baseline will be followed by three follow-up surveys of the target audience of young adults at approximately 6-month intervals after the campaign's launch. Information will be collected about young adult awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions and use, as well as use of other tobacco products (e-cigarettes, hookah, cigars, smokeless tobacco), marijuana and alcohol. Information will also be collected on demographic variables including sexual orientation, age, sex, race/ethnicity, education, and primary language.

All information will be collected through in-person and web-based questionnaires. Young adult respondents will be recruited in 30 U.S. cities (15 campaign and 15 comparison cities) from two sources: (1) Intercept surveys in LGBT social venues (*e.g.,* bars and nightclubs) identified using a time location sampling approach, and (2) through social media advertisements on Facebook and Twitter targeted at LGBT 18 to 24-year-olds, living in the same 30 U.S. cities. Participation in the study is voluntary.

- Media Tracking Survey

The media tracking survey consists of assessments of LGBT young adults aged 18 to 24 conducted once yearly post campaign launch—timing that complements the outcome evaluation's timing. The media tracking survey will assess awareness of the campaign and receptivity to campaign messages. These data will provide critical evaluation feedback to the campaigns and will be conducted with sufficient frequency to match the cyclical patterns of events and media advertising and variation in exposure to allow for mid-campaign refinements. For the media tracking surveys, we will recruit LGBT young adults aged 18 to 24 from all campaign cities through social media.

The information collected is necessary to inform FDA's efforts and measure the effectiveness and public health impact of the campaigns. Data from the media tracking surveys will be used to estimate awareness of and exposure to the campaigns among young adults in target markets where the campaigns are active. Data from the outcome evaluation study will be used to examine statistical associations between awareness of and exposure to the campaigns and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, beliefs and intentions related to tobacco use.

FDA's burden estimate is based on prior experience with in-person studies similar to the Agency's plan presented in this document, as well as previous

research using social media advertising to recruit young adult participants. To reduce overall burden hours, participants who screen and complete the baseline outcome evaluation questionnaire will be re-contacted to complete the first follow up campaign evaluation questionnaire, those who complete the first follow up campaign evaluation questionnaire will be re-contacted to complete the second follow up campaign evaluation questionnaire, and so on. Re-contacted individuals will not need to complete the screener again. We expect a 50 percent response rate for individuals recruited in person and a 30 percent rate for individuals recruited via social media. In each successive round of data collection, we expect 50 percent of re-contacted individuals to complete the follow up questionnaire, therefore, additional screenings will be conducted for each follow up in order to maintain the target sample size for each follow up questionnaire.

To obtain the target number of completed questionnaires (''completes'') for the outcome evaluation study, 18,376 young adults (11,810 recruited in person and 6,566 recruited via social media) will participate in a screening process (''screener''). The estimated burden per screener is 5 minutes (0.083), for a total of 1,525 hours (980 hours for participants recruited in person and 545 hours for persons recruited via social media). A total of 12,600 LGBT young adults (9,448 of those screened in person and 3,152 of those screened through social media) will complete questionnaires in 4 rounds of data collection (baseline and three post-campaign rounds). The estimated burden per complete is 30 minutes (0.5 hour) for the baseline questionnaire and 40 minutes (0.667 hour) for each follow up complete, for a total of 7,878 hours (5,906 hours for those recruited in person and 1,972 hours for those recruited via social media).

To obtain the target number of completes for the media tracking survey, 5,000 young adults will be recruited via social media ads to complete a screener for all three waves of the media tracking survey. The estimated burden per screener response is 5 minutes (0.083 hour), for a total of 414 hours for all waves of media tracking screener. An estimated 500 LGBT young adults will complete each of the three waves of the media tracking survey (assuming a 30 percent response rate to screeners via social media). The estimated burden per completed media tracking questionnaire is 40 minutes (0.667 hour), for a total of 1,002 hours for the three waves. The total burden for the media tracking survey (screeners and completes) is 1,416 hours.

The target number of completed campaign questionnaires (screeners and questionnaires for both the outcome evaluation and media tracking survey) for all respondents is 37,477. The total estimated burden is 10,819 hours.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General population—Recruited in person (50% response rate).	Screener—Baseline—outcome study.	4,724	1	4,724	0.083 (5 min.)	392
	Screener—First follow up—outcome study.	2,362	1	2,362	0.083 (5 min.)	196
	Screener—Second follow up—outcome study.	2,362	1	2,362	0.083 (5 min.)	196
	Screener—Third follow up—outcome study.	2,362	1	2,362	0.083 (5 min.)	196
LGBT young adults aged 18–24 in select media markets—Recruited in person.	Baseline—outcome evaluation questionnaire.	2,362	1	2,362	0.5 (30 min.)	1181
	First follow up young adult outcome evaluation questionnaire.	2,362	1	2,362	0.667 (40 min.)	1575
	Second follow up young adult outcome evaluation questionnaire.	2,362	1	2,362	0.667 (40 min.)	1575
	Third follow up young adult outcome evaluation questionnaire.	2,362	1	2,362	0.667 (40 min.)	1575
General population—Recruited via social media (30% response rate).	Screener—Baseline—outcome study.	2,627	1	2,627	0.083 (5 min.)	218
	Screener—First follow up—outcome study.	1,313	1	1,313	0.083 (5 min.)	109
	Screener—Second follow up—outcome study.	1,313	1	1,313	0.083 (5 min.)	109
	Screener—Third follow up—outcome study.	1,313	1	1,313	0.083 (5 min.)	109
LGBT young adults aged 18–24 in select media markets—Recruited via social media.	Baseline—outcome evaluation questionnaire.	788	1	788	0.5 (30 min.)	394
	First follow up young adult outcome evaluation questionnaire.	788	1	788	0.667 (40 min.)	526

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	Second follow up young adult outcome evaluation questionnaire.	788	1	788	0.667 (40 min.)	526
	Third follow up young adult outcome evaluation questionnaire.	788	1	788	0.667 (40 min.)	526
LGBT young adults aged 18–24 in the select media markets—Recruited via social media.	1st media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	1st media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
	2nd media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	2nd media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
	3rd media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	3rd media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
Total	.....	37,477	.....	.....	.....	10,819

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16020 Filed 6–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

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 these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by August 31, 2015.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, 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 draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register.** The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register.** FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on March 9, 2015 (80 FR 12502). This notice announces draft product-specific