FDA is specifically seeking feedback on the following issues:

- Please comment on the definition of the meal content. Should meal types be defined solely by the calorie and fat content, or should carbohydrates and proteins also be included?
- Please comment on the definition of the low-fat meal. Are the 400–500 calories and 25 percent fat a sufficient definition of a low-fat meal (refer also to table 2)?
- Please comment on the Biopharmaceutics Classification System-based waiver for food-effect trials. Does current science support this biowaiver?

Information on fed bioequivalence (BE) studies to be submitted in abbreviated new drug applications (ANDAs) can be found in the FDA draft guidance for industry entitled ''Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' Specific recommendations concerning fed comparability trials are now found in the FDA draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' When finalized these guidances will represent the current thinking of FDA on these topics.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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 part 314 (21 CFR part 314), including §§ 314.50 and 314.94, have been approved under OMB control number 0910–0001. The collections of information in part 312 (21 CFR part 312), including § 312.23, have been approved under OMB control number 0910–0014. The collection of information in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information related to pharmacogenomic data have been approved under OMB control number 0910–0557.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03247 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0143]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

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 March 28, 2019.

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 0910–0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Foreign Supplier Verification Programs (FSVP) for Food Importers

OMB Control Number 0910–0752—Extension

This information collection supports FDA regulations at 21 CFR part 1, subpart L—Foreign Supplier Verification Programs for Food Importers, as well as associated guidance. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. The regulations are intended to help ensure that food imported into the United States is produced in compliance with specific processes and procedures, including reasonably appropriate risk-based preventive controls. The regulations establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances that a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions.

To assist respondents with understanding the regulatory requirements, we have developed Agency guidance, which is available at: *https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.*

In the **Federal Register** of October 22, 2018 (83 FR 53271), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section(s)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with U.S. Customs and Border Protection 1.509, 1.511, 1.512.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity; 21 CFR section(s)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
FSVP Recordkeeping, including hazard determination, written procedures, reevaluation; audits; and corrective actions:					
Determine and document hazards; 1.504(a)	11,701	1	11,701	3.5	40,954
Review hazard analysis; 1.504(d)	11,701	7	81,907	0.33 (20 minutes)	27,029
Evaluation of food and foreign supplier; 1.505(a)(2), 1.511(c)(1).	11,701	1	11,701	4	46,804
Approval of suppliers; 1.505(b), 1.512(c)(1)(iii)	8,191	1	8,191	12	928,292
Reevaluation of food and foreign supplier; 1.505(c), 1.512(c)(1)(ii)(A).	11,701	365	4,270,865	0.25 (15 minutes)	1,067,716
Confirm or change requirements of foreign supplier verification activity; 1.505(c), 1.512(c)(1)(ii)(A).	2,340	1	2,340	2	4,680
Review of other entities assessments; 1.505(d), 1.512(c)(1)(iii).	3,510	1	3,510	1.2	4,212
Written procedures for use of approved foreign suppliers; 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i).	11,701	1	11,701	8	93,608
Review of written procedures; 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii).	11,701	1	11,701	1	11,701
Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3).	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)–(2) 1.511(c)(5)(i).	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3) 1.511(c)(5)(iii).	11,701	2	23,402	0.33 (20 minutes)	7,723
Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(4)(ii)(A).	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(4)(ii)(B).	11,701	2	23,402	1	23,402
Review records; 1.506(e)(1)(iii), 1.511(c)(4)(ii)(C)	11,701	2	23,402	1.6	37,443
Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(4)(iii).	11,701	6	70,206	0.25 (15 minutes)	17,552
Document hazard controls; 1.507(a)(1)	11,701	3.17	37,092	1.25	46,365
Written assurances; 1.507(a)(2), (a)(3), and (a)(4).	11,701	8.72	102,038	0.50 (30 minutes)	51,019
Disclosures that accompany assurances; 1.507(a)(2), (a)(3), and (a)(4).	102,038	1	102,038	0.50 (30 minutes)	51,019
Document assurances from customers; 1.507(c)	36,522	2.8	102,262	0.25 (15 minutes)	25,566
Document corrective actions; 1.508(a), 1.512(b)(4).	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1).	2,340	1	2,340	5	11,700
Subtotal for FSVP Recordkeeping Itemized Above.			4,984,046		1,917,186
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511(b).	11,701	2.88	33,699	2.25	75,823
Document very small importer/certain small foreign supplier status; 1.512(b)(1).	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3).	50,450	2.8	141,260	2.25	317,835

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Information collection activity; 21 CFR section(s)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					2,361,294

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

We are retaining the currently approved burden estimates. The FSVP requirements became effective May 30, 2017, and we continue to evaluate associated burden.

Dated: February 21, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03282 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Opportunity To Co-Sponsor OMH National Minority Health Month Steps Challenge

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office of Minority Health (OMH), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: OMH announces the opportunity for public and non-profit entities to co-sponsor the National Minority Health Month National Steps Challenge for April 2019. Potential co-sponsors must have a demonstrated interest in reducing health disparities among minority communities, advancing the HHS Physical Activity Guidelines and improving the health of Americans through promoting regular physical activity.

DATES: To receive consideration for this opportunity, a two-page proposal to participate as a co-sponsor must be received by OMH by 5 p.m. EST on March 7, 2019 at the address listed below. Co-sponsorship proposals will meet the deadline if they are either (1) received or (2) postmarked on or before the deadline. Privately metered postmarks will not be accepted as proof of timely mailing. Proposals received after the established deadline will not be considered.

ADDRESSES: Proposals for co-sponsorship should be sent to Mr. Anthony Welch, HHS Office of Minority Health, 1101 Wootton Parkway, Suite 600, Tower Building, Rockville, Maryland 20852. Requests may also be emailed to *Anthony.Welch@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Welch, HHS Office of Minority Health Quality, 1101 Wootton Parkway, Suite 600, Tower Building, Rockville, Maryland 20852; (240) 453–2882.

SUPPLEMENTARY INFORMATION: The mission of the Office of Minority Health (OMH) at the U.S. Department of Health and Human Services (HHS) is to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. Key strategies of the OMH mission include:

- Developing and promoting policies, programs and practices to achieve health equity;
- Funding demonstration programs at the regional, state and local level that can contribute to health policy and the effectiveness of strategies for improving health;
- Improving data collection, reporting and sharing for ethnic and racial minority populations;
- Fostering research and evaluation; and
- Establishing and strengthening networks, coalitions and partnerships to identify and solve health problems.

OMH observes National Minority Health Month every year in April to highlight the health disparities that persist among racial and ethnic minority populations and the ways in which policies, programs and partnerships can help advance health equity. The HHS OMH establishes the national theme and serves as the lead HHS office for the observance of National Minority Health Month.

The theme for 2019 is Active & Healthy and is intended to help promote the second edition of the HHS Physical Activity Guidelines and the Move Your Way Campaign from the HHS Office of Disease Prevention and Health Promotion, especially among racial and ethnic minorities. OMH's main activity for this year's observance is the National Minority Health Month Steps Challenge (Challenge). The Challenge will occur throughout the month of April and OMH will enlist teams and individuals to participate from federal, state and local governments, community-based organizations and tribal communities, who want to show their commitment to an active lifestyle. Activities and materials throughout the month will highlight the overall message that physical activity promotes health and reduces the risk of chronic disease.

Eligibility for Co-Sponsorship

To be eligible, a potential co-sponsor shall: (1) Have a demonstrated understanding, commitment, and experience in conducting large-scale steps challenges; (2) be knowledgeable about strategies to promote health & active lifestyles; (3) have a track record and the ability to manage an online platform to host multiple teams in the challenge; (4) participate substantively in the co-sponsored activity, not just provide logistical support; and (5) have an organizational mission that is consistent with OMH and HHS. The selected co-sponsoring organization shall furnish the necessary personnel, materials, services, and facilities to administer its proposed portion of the responsibility for the Challenge. These duties will be outlined in a co-sponsorship agreement with OMH that will set forth the details of the co-sponsored activity.

Co-Sponsorship Proposal

Each co-sponsorship proposal shall contain a description of: (1) The entity or organization's background and history; (2) its ability to satisfy the co-sponsorship criteria detailed above; and (3) its proposed involvement in the co-sponsored activity. The co-sponsorship proposal should not exceed two (2) pages in length and should be double-spaced in Times New Roman.

Evaluation Criteria

After engaging in exploratory discussions with potential co-sponsors that respond to this notice, representatives of OMH will select the co-sponsor using the following evaluation criteria:

(1) Qualifications and capability to fulfill co-sponsorship responsibilities;

(2) Creativity related to enhancing the National Minority Health Month event;

(3) Potential for reaching and generating participants from among key stakeholders, including federal, state and local organizations, member-based organizations and the general public.