information. Four comments were received. Three comments pertain to the information collection. One comment addressed an issue unrelated to the proposed collection of information, such as pet food safety; therefore, we do not address this issue in this document.

One comment expressed concern that the estimated hours to collect the information required to implement and maintain the requirements in the draft feed standards is low. Two comments expressed concern that implementing and maintaining the draft feed standards would require more State program employees and financial support from FDA.

Regarding the comment asserting that the total estimated hours reported in Table 1 is low; we recognize the number of hours needed to implement and maintain the draft feed standards will vary among States depending on the size of the State's feed program, the number of staff, and the State's short and long term goals for implementing the draft feed standards. The burden estimates are reasonable given the variation among State programs and their current ability to implement the draft feed standards.

Regarding the comment expressing concern that the State feed programs would need additional employees and funding from FDA to implement and maintain the requirements in the draft feed standards; FDA recognizes that State feed programs may need additional resources to implement and maintain the draft feed standards. Therefore, FDA will pursue funding for the draft feed standards; however, the level of funding may vary each year and is contingent on budget approval.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
State Feed Regulatory Programs in the United States	50	1	50	3,000	150,000

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

The burden has been calculated to 3,000 hours per respondent. The estimate includes time for reviewing the draft feed standards, gathering and maintaining the data and documents for each standard, and completing and reviewing the data and documents that would be spent to fully implement the 11 standards. FDA recognizes that full use and implementation of the draft feed standards by State feed programs will occur over many years and the number of years to fully implement the draft feed standards will vary among States. This burden was determined by averaging the burden estimates received from five respondents. The five respondents are representative of the State feed programs in the United States.

Dated: November 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26778 Filed 11–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Sixth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Sixth Annual Sentinel Initiative.'' Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the status of FDA's Sentinel Initiative and future plans, highlights from key Mini-Sentinel and related activities, and an update on active surveillance collaborations and program extensions. In addition, this workshop will engage stakeholders to discuss current and emerging Sentinel projects and facilitate stakeholder feedback and input on Sentinel projects that would be appropriate to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action (e.g., labeling changes, postmarketing requirements (PMRs), or postmarketing commitments (PMCs)). This workshop satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

Date and Time: The public workshop will be held on January 14, 2014, from 9 a.m. to 4 p.m.

Location: The public workshop will be held at the Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC 20001. For additional travel and hotel information, please refer to *http://www.cvent.com/d/jcqhyy.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Contact Person: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before January 14, 2014, by visiting *http://www.cvent.com/d/jcqhyy.* Early registration is recommended. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. There is no registration fee for the public workshop; but because seating is limited, registration will be on a first-come, first-served basis. A 1-hour lunch break is scheduled; however, food will not be provided. There are multiple restaurants within walking distance of the hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (email: *jKlatzman@brookings.edu*) at least 7 days in advance.

Meeting Materials: All event materials will be available to registered attendees via email prior to the workshop and will be posted after the event on the

Brookings Institution event Web site at *http://www.brookings.edu//health/events.*

Transcripts: Please be advised that transcripts will not be available.

SUPPLEMENTARY INFORMATION: On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represent FDA's commitments during fiscal years 2013–2017 (PDUFA V). These commitments are fully described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017'' (PDUFA Goals Letter), available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.* Section XI of the PDUFA Goals Letter, entitled ''Enhancement and Modernization of the FDA Drug Safety System,'' includes Sentinel as a tool for evaluating drug safety issues that may require regulatory action. As part of this enhancement, FDA committed to hold a public meeting to engage stakeholders in a discussion of current and emerging Sentinel projects and facilitate stakeholder feedback and input to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action, e.g., labeling changes, PMRs, or PMCs. The public workshop announced by this notice will fulfill this commitment.

Dated: November 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26855 Filed 11–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1317]

Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: Based on new scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA) has tentatively determined that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced *trans* fatty acids, or *trans* fat, are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence establishing the health risks associated with the consumption of *trans* fat, and therefore that PHOs are food additives. Although FDA has not listed the most commonly used PHOs, they have been used in food for many years based on self-determinations by industry that such use is GRAS. If finalized, this would mean that food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, without prior FDA approval for use as a food additive.

DATES: Submit either electronic or written comments and scientific data and information by January 7, 2014.

ADDRESSES: Submit electronic comments and scientific data and information to *http://www.regulations.gov.* Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions must include the Agency name and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1278, FAX: 301–436–2972, email: *mical.honigfort@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

In accordance with the process set out in § 170.38(b)(1) (21 CFR 170.38(b)(1)), we are issuing this document announcing our tentative determination that PHOs are no longer GRAS under any condition of use in food and therefore are food additives subject to section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348). If finalized, this would mean that food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, without prior FDA approval for use as a food additive.

FDA's evaluation of the GRAS status of PHOs is centered on the *trans* fatty acid (also referred to as ''*trans* fat'') component of these oils. This document addresses PHOs because they are the primary dietary source of industrially-produced *trans* fat (Ref. 1). Although all refined edible oils contain some *trans* fat as an unintentional byproduct of their manufacturing process, *trans* fats are an integral component of PHOs and are purposely produced in these oils to affect the properties of the oil and the characteristics of the food to which they are added.

The current scientific evidence, which is discussed in section IV of this document, identifies significant health risks caused by the consumption of *trans* fat. This evidence includes the opinions of expert panels and the 2005 recommendation of the Institute of Medicine (IOM) to limit *trans* fat consumption as much as possible while consuming a nutritionally adequate diet, recognizing that *trans* fat occurs naturally in meat and dairy products from ruminant animals and that naturally-occurring *trans* fat is unavoidable in ordinary, nonvegan diets without significant dietary adjustments that may introduce undesirable effects (Ref. 2). In addition, according to the Centers for Disease Control and Prevention (CDC), elimination of PHOs from the food supply could prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths annually, if the marginal benefits of continuing to remove trans fats from food items remain constant (Ref. 3). (See accompanying economic analysis for more information on this estimate.) Given this evidence, we have tentatively determined that there is no longer a consensus among qualified scientific experts that PHOs, the primary dietary source of industrially-produced *trans* fatty acids, are safe for human consumption, either directly or as ingredients in other food products.

II. Background

A. Hydrogenation Process and Trans Fatty Acids

Chemical hydrogenation is the process by which hydrogen atoms are added to unsaturated sites on the carbon chains of fatty acids, in the presence of catalysts, thereby reducing the number of double bonds. ''Partial hydrogenation'' describes an incomplete saturation of the double bonds, in which some double bonds remain but may shift to a different position along the carbon chain and alter their configuration from *cis* to *trans.* The *trans* arrangement of hydrogen atoms results in a relatively straight configuration of the fatty acids and increases the melting point, shelf life,