DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–21727 Filed 9–1–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

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 notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act (PHS Act.)

DATES: Submit either electronic or written comments on the collection of information by November 2, 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, including each proposed extension of an existing 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: (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.

Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0734)—Extension

Section 505(o)(4) of the FD&C Act (21 U.S.C. 355(o)(4)) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) imposes timeframes for application holders to submit and FDA staff to review such changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes. The guidance provides information on the implementation of the new provisions, including a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how FDA plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes.

FDA requires safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

Based on FDA's experience to date with safety labeling changes requirements under section 505(o)(4), we estimate that approximately 42 application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the guidance, FDA states that new labeling prepared in

response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval. FDA estimates that approximately 407 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	42	1	42	6	252

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Posting approved labeling on application holder's Web site	407	1	407	4	1,628

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

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21645 Filed 9–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Food and Drug Administration/Drug Information Association Oligonucleotide-Based Therapeutics Conference 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in cosponsorship with the Drug Information Association (DIA), is announcing a meeting entitled ''FDA/DIA Oligonucleotide-Based Therapeutics Conference 2015'' (FDA/DIA 2015 conference). The purpose of the meeting is to discuss advances, safety, and challenges in the field of oligonucleotide-based therapeutics.

DATES: The meeting will be held on September 9 to September 10, 2015, from 7 a.m. to 5 p.m. and September 11, 2015, from 7 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Meredith Kaganovskiy, Drug Information Association (DIA), 800 Enterprise Rd., Horsham, PA 19044, 215–442–6117, FAX: 215–293–5923, email: *Meredith.kaganovskiy@diaglobal.org;* or Robert T. Dorsam, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 301–796–1623, email: *robert.dorsam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Oligonucleotide therapeutics constitute a diverse and evolving class of drug products that are being developed for a wide variety of indications. The FDA/DIA 2015 conference is a forum where regulators, academics, and members of industry will discuss the advances, challenges, and opportunities in the field of oligonucleotide therapeutics. This is the sixth meeting in approximately eight years where attendees will discuss oligonucleotide therapeutics in clinical, nonclinical, and chemistry tracks. The meeting will provide updates on advancements in this field, and will also present time for stakeholders to discuss challenges in the development and regulation of oligonucleotide therapeutics. Topics will be addressed using presentations, panel discussions, case studies, and a poster session to facilitate discipline-specific and multidisciplinary discussions. The goal of the meeting is to provide a current view of oligonucleotide therapeutics and foster advancement in the field through discussions among regulators, academics, and industry members.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of facilities, meeting materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.diaglobal.org/.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$1,350
Charitable Nonprofit/Academic	675
Government	405

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Grand Hyatt Washington are eligible for a reduced rate of $209, not including applicable taxes. This rate is available for a limited number of rooms. To receive the reduced rate, hotel reservations must be made with onPeak and not directly with the hotel. Contact information for onPeak is as follows: Toll free in the United States 1–855–355–0302 or 1–212–532–1660. When calling, please select option 1 for ''Hotel Reservations,'' and inform the phone agent that you are making a reservation for Event #15011.

If you need special accommodations due to a disability, please contact Meredith Kaganovskiy (DIA) or Robert.