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

21 CFR part 112	Number of respondents	Number of disclosures per respondent	Total disclosures	Average burden per disclosure	Total hours
Disclosure under §§ 112.2, 112.6, 112.31, 112.33, and 112.142	77,165	3.459	266,914	1.422	379,551

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

Section 112.7 (21 CFR 112.7) requires farms eligible for the qualified exemption in accordance with § 112.5 (21 CFR 112.5) to maintain the records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption, including a written record reflecting that the owner, operator, or agent in charge of the farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. We estimate that 3,285 farms are eligible for the qualified exemption and that each farm will spend an average of 0.5 hours per year to maintain one record. Therefore, 3,285 recordkeepers × 0.5 average hours per recordkeeping = 1,642.5 hours (rounded to 1,643) to meet the recordkeeping requirements of § 112.7.

Section 112.30 (21 CFR 112.30) requires the maintenance of records of required training of personnel, including the date of training, topics covered, and persons trained. We estimate that 24,420 farms maintain one record of required training and spend an average of 7.25 hours per year on recordkeeping. Therefore, 24,420 recordkeepers × 7.25 average hours per recordkeeping = 177,045 hours to meet the recordkeeping requirements of § 112.30.

Although compliance dates for the agricultural water provisions (subpart E) for covered produce other than sprouts are delayed to January 26, 2024, for very small businesses, January 26, 2023, for small businesses, and January 26, 2022, for all other businesses, we have estimated the burden. Section 112.46 (21 CFR 112.46) requires testing agricultural water subject to the requirements of §§ 112.44 and 112.45 (21 CFR 112.44 and 112.45). We estimate that 48,361 farms that will conduct these tests. Thus, it is estimated that about three (2.990) records for each farm will spend an average of 0.825 hours per record on testing water. Therefore, 48,361 farms × 2.990 records × 0.825 average hours per recordkeeping = 119,294.175 hours (rounded to 119,294) to meet the recordkeeping requirements of §§ 112.44 and 112.45.

For records related to agricultural water, we estimate that there are 160,605 recordkeepers each maintaining just over 2 records (2.242), with each recordkeeping taking just over 2 hours (2.160). Therefore, 160,605 recordkeepers × 2.242 records × 2.160 hours = 777,765.046 hours (rounded to 777,765) for the recordkeeping burden related to agricultural water.

Sections 112.144, 112.145, and 112.147 (21 CFR 112.144, 112.145, and 112. 147) require testing for sprouts. We estimate that 126 recordkeepers will maintain records for these tests. Thus, it is estimated that for about 246 (245.660) records each recordkeeper will spend an average of 0.825 hour per record on testing sprouts. Therefore, 126 recordkeepers × 245.660 records × 0.825 average hours per recordkeeping = 25,536.357 hours (rounded to 25,536) to meet the recordkeeping requirements of §§ 112.144, 112.145, and 112.147.

We estimate that there are 126 recordkeepers for other records related to sprouts. Thus, it is estimated that for about 62 (62.061) records each recordkeeper will spend an average of 1.412 hours per record. Therefore, 126 recordkeepers × 62.061 records × 1.412 average hours per recordkeeping = 11,041.397 (rounded to 11,041) hours for the burden to maintain records related to sprouts.

We estimate 126 recordkeepers will utilize the recommendations in the draft guidance document entitled ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations,'' once finalized, to maintain additional records related to sprouts. We estimate each recordkeeper will keep 233 records and recordkeeping will take about an hour per record for a recordkeeping burden of 29,358 hours.

Section 112.2 relates to documentation supporting compliance. We estimate that there are 4,568 recordkeepers each maintaining a record of compliance. We estimate that each recordkeeper will spend 0.079 hour maintaining their record. Therefore, 4,568 recordkeepers × 0.079 hour = 360.872 (rounded to 361) hours for the burden to maintain documentation supporting compliance.

Sections 112.2, 112.6, 112.31, 112.33, and 112.142 (21 CFR 112.2, 112.6, 112.31, 112.33, and 112.142) require third-party disclosures. We estimate that 77,165 respondents are making these disclosures. Thus, it is estimated that each respondent has around three (3.459) disclosures and will spend an average of 1.422 hours per disclosure. Therefore, 77,165 respondents × 3.459 disclosures × 1.422 average hours per disclosure = 379,551.331 hours (rounded to 379,551) for the third-party disclosure burden to meet the requirements of §§ 112.2, 112.6, 112.31, 112.33, and 112.142.

The burden estimate reflects adjustments resulting in an overall increase of 8,515 hours. Although we removed the one-time burden that has been realized since establishing the regulations, we have added burden attributed to recommendations found in the Sprouts draft guidance.

Dated: June 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12108 Filed 6–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4735]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 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 10, 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 0910–0734. 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.

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 Federal Food, Drug, and Cosmetic Act (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 it 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 Public Health Service Act (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) establishes time frames by which application holders must submit, and FDA staff must review, information necessary to ensure timely and appropriate labeling changes. To communicate how we implement these provisions we developed the guidance entitled ''Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act,'' which provides instruction on: (1) A description of the types of safety labeling changes that ordinarily might be required; (2) how FDA plans to determine what constitutes new safety information; (3) the procedures involved in requiring safety labeling changes, and (4) enforcement of the requirements for safety labeling changes. The guidance is currently posted to the docket and available on FDA's website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-labeling-changes-implementation-section-505o4-federal-food-drug-and-cosmetic-act.*

As explained in the guidance, we send application holders a notification letter when safety labeling changes are required. Under section 505(o)(4)(B) of the FD&C Act, the application holder must respond to our notification by either submitting a labeling supplement, or a rebuttal statement explaining why it believes the labeling change is unwarranted. Based on our experience to date with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, we estimate that 36 application holders will elect to submit 1 rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, the guidance explains that labeling prepared in response to a safety labeling change notification should be available on the application holder's website within 10 calendar days of approval. We estimate that 351 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.

In the **Federal Register** of February 12, 2019 (84 FR 3461), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. The comment offered general support for the information collection, provided certain statistical details regarding potential respondents, encouraged utilization of electronic and/or digital technology where possible, and offered a related topic for which additional guidance might be useful. We appreciate the comment and will continue to consider the suggestions provided. At the same time, it was not suggested that we make changes to our burden estimate, which remains as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	36	1	36	6	216

[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 approval labeling on application holder's website	351	1	351	4	1,404

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

Since last OMB review and approval, we have adjusted our estimated annual number of respondents downward by 62. The decrease reflects that we have issued fewer safety labeling notifications, and thus fewer postings

are required and fewer rebuttals are expected.

Dated: June 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12109 Filed 6–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Leveraging Randomized Clinical Trials To Generate Real-World Evidence for Regulatory Purposes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes.'' Convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke Margolis) and supported by a cooperative agreement with FDA, the purpose of the public workshop is to bring the stakeholder community together to explore key considerations for using randomized designs, such as large simple trials or those that incorporate pragmatic elements to generate real-world evidence (RWE).

DATES: The public workshop will be held on July 11, 2019, from 8:30 a.m. to 5 p.m., Eastern Time and July 12, 2019, from 9 a.m. to 1 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at The Westin City Center, 1400 M St. NW, Washington, DC 20005. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3022 of the 21st Century Cures Act (Cures Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 505F, *Utilizing real world evidence* (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help to support or satisfy postapproval study requirements. In December 2018, FDA published the Framework for the RWE program (*https://www.fda.gov/media/120060/download*). To inform FDA's RWE Framework, on September 13, 2017, through its cooperative agreement with Duke Margolis, FDA convened a public meeting that explored the use of RWE for regulatory decisions.

The RWE Framework includes information describing sources of RWE, gaps in data collection activities, standards and methodologies for collecting and analyzing RWE, and priority areas, remaining challenges, and potential pilot opportunities to address the overarching Cures Act requirements. The RWE Framework also discusses the integration of clinical trials into clinical care settings and FDA's intent to issue guidance on this subject. The public workshop announced in this notice is a part of FDA's ongoing efforts to implement the RWE Framework by exploring the utility of RWE for regulatory decision making. This workshop will focus on how randomized clinical trial designs can use real-world data (RWD) to generate RWE, particularly in clinical care settings.

II. Topics for Discussion at the Public Workshop

This workshop will explore key considerations for using randomized clinical trial designs and RWD to generate RWE, particularly in clinical care settings. Considerations for discussion include: (1) Selection of interventions appropriate in clinical care settings, (2) study design elements and study populations, (3) capturing outcomes in clinical care settings, and (4) addressing potential challenges around blinding, randomization, and bias. The workshop will also explore regulatory considerations for randomized clinical trials using RWD, such as safety and product monitoring and maintaining data integrity.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*. There will be no onsite registration. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by July 10, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been registered. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (phone: 202–791–9561, email: *sarah.supsiri@duke.edu*) no later than July 5, 2019.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast, and archived video footage will be available at the Duke-Margolis website (*https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*) following the workshop. Persons interested in viewing the live webcast are encouraged to register in advance (see *Registration*). Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and publicly available at the Duke-Margolis website (*https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*).

Transcripts: Transcripts of the public workshop will not be available.