DCH-Performance Monitoring Database (DCH–PMD). Forty-four previously funded *Partnership to Improve Community Health* awardees will no longer be included in this collection due to funding cessation.

The information system collects information to enable the accurate, reliable, uniform and timely submission to CDC of each awardee's work plan and progress reports. Monitoring allows CDC to: (1) Determine whether an awardee is meeting performance goals; (2) make adjustments in the type and level of technical assistance provided to awardees; and (3) provide oversight of the use of federal funds.

CDC also requests OMB approval to conduct targeted, special purpose information collections on an as-needed basis. Due to substantial interest in the *REACH* program from a variety of stakeholders, CDC estimates that each *REACH* awardee may receive an invitation to participate in one special purpose information collection. Methods for these data collections could include telephone interviews, in-person interviews, Web-based surveys, or paper-and-pencil surveys. CDC will submit each special-purpose information collection request to OMB for approval through the Change Request mechanism, and will include the data collection instrument(s) and a description of purpose and methods.

CDC seeks approval for one year to collect the necessary data. Also, CDC requires cooperative agreement awardee semi-annual progress reporting participation, but voluntary for some special-purpose data collections.

There are no costs to respondents other than their time. CDC estimates no change to the average burden per response for routine, semi-annual reporting (estimated at three hours). The total estimated annualized burden hours for an additional year of information collection are 588.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
DCH Program Awardees (state, local and tribal government sector).	DCH MIS: Semi-annual reporting	18	2	3
	Special Data Request	18	1	6
DCH Program Awardees (private sector)	DCH MIS: Semi-annual reporting	31	2	3
	Special Data Request	31	1	6

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–03803 Filed 2–23–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1119; FDA–2010–N–0622; FDA–2011–N–0019; FDA–2010–N–0594; FDA–2011–N–0016; FDA–2009–N–0501; FDA–2014–N–0222; FDA–2017–D–0040; and FDA–2016–N–3585]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified and Thermally Processed Low-Acid Foods	0910–0037	10/31/2020
Color Additive Certification Requests and Recordkeeping	0910–0216	10/31/2020
Customer/Partner Service Surveys	0910–0360	10/31/2020
Focus Groups as Used by the Food and Drug Administration	0910–0497	10/31/2020
Recordkeeping and Records Access Requirements for Food Facilities	0910–0560	10/31/2020
Reporting and Recordkeeping Requirements for Reportable Food	0910–0643	10/31/2020
Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	0910–0693	10/31/2020

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Draft Guidance for Industry; How to Prepare a Pre-Request for Designation (Pre-RFD)	0910–0845	10/31/2020
Character-Space-Limited Online Prescription Drug Communications	0910–0846	10/31/2020

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03849 Filed 2–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0436]

Q11 Development and Manufacture of Drug Substances—Questions and Answers (Chemical Entities and Biotechnological/Biological Entities); International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''Q11 Development and Manufacture of Drug Substances—Questions and Answers (Chemical Entities and Biotechnological/Biological Entities).'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance consists of questions and answers that were developed to clarify the principles for selecting starting materials described in the ICH guidance ''Q11 Development and Manufacture of Drug Substances'', published November 20, 2012. The guidance is intended to provide additional clarification and to promote convergence on the considerations for the selection and justification of starting materials. The questions and answers focus on chemical entity drug substances, and provide recommendations on the information that should be provided in marketing authorization applications and/or master files to justify the starting materials.

DATES: The announcement of the guidance is published in the **Federal Register** on February 26, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–D–0436 for ''Q11 Development and Manufacture of Drug Substances—Questions and Answers (Chemical Entities and Biotechnological/Biological Entities).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,