developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

FDA estimates the burden of this collection of information based on prior experience with the various types of data collection methods described above:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 393(d)(2)(D)	9,280	1	9,280	0.2935 (17 min.)	2,724

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

Dated: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–23791 Filed 9–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) 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 information collection in the guidance on citizen petitions and petitions for stay of action subject to of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by December 2, 2013.

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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 these topics: (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 Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910–0679)—Extension

In the **Federal Register** of June 8, 2011(76 FR 33309), FDA announced the availability of a guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' The guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) (U.S.C. 355(b)(2) or U.S.C. 355(j)) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending abbreviated new drug application (ANDA) or a section 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition

include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and section 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112–144, 126 Stat. 993). Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened FDA's deadline from 180 days to 150 days for responding to petitions subject to section 505(q) of the FD&C Act. Second, it expanded the scope of section 505(q) of the FD&C Act to include certain petitions concerning applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, we are now including submissions pertaining to biosimilar biological product applications in the information collection burden estimates below.

Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of agency action include a verification to be accepted for review by FDA. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) of the FD&C Act apply to a particular citizen petition or petition for stay of agency action. The guidance states that one of the criteria for a citizen petition or petition for stay of agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or section 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or section 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or section 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or section 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act and the petitioner would like FDA to review the citizen petition or petition for stay of agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB control number 0910–0183). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b) (21 CFR 10.30(b))); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b) (21 CFR 10.35(b))); and (5) the submission of written comments on a filed petition for administrative stay of action (§ 10.35(c)). This information collection includes citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described previously in this document, which are subject to section 505(q) of the FD&C Act and described in the guidance.

We are requesting OMB approval for the following collection of information submitted to FDA under section 505(q) of the FD&C Act and the guidance:

1. The certification required under section 505(q)(1)(H) of the FD&C Act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, section 505(b)(2) application, or biosimilar biological product application. Although the submission of a certification for citizen petitions is approved under OMB control number 0910–0183, the certification would be broadened under section 505(q) of the FD&C Act and the guidance.

2. The certification required under section 505(q)(1)(H) of the FD&C Act for petitions for stay of agency action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, section 505(b)(2) application, or biosimilar biological product application.

3. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to citizen petitions.

4. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to petitions for stay of agency action.

5. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.

6. Supplements to petitions for stay of agency action.

7. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of agency action.

8. The letter submitted by a petitioner withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA, section 505(b)(2) application, or biosimilar biological product application is necessary based on a petition subject to section 505(q), the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB control number 0910–0001.

Based on FDA's knowledge of citizen petitions and petitions for stay of agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the Agency's familiarity with the time needed to prepare a supplement, a certification, and a verification, FDA estimates the burden of this collection of information 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
Certification for citizen petitions (505(q)(1)(H))	26	1.15	32	0.5 (30 min.)	16
Certification for petitions for stay of agency action (505(q)(1)(H)).	1	1	1	0.5 (30 min.)	.5
Verification for comments to citizen petitions (505(q)(1)(I)).	9	1.33	12	0.5 (30 min.)	6.0
Verification for comments to petitions for stay of agency action (505(q)(1)(I)).	1	1	1	0.5 (30 min.)	.5
Verification for supplements to citizen petitions (505(q)(1)(I)).	7	1.43	10	0.5 (30 min.)	5.0
Supplements to petitions for stay of agency action	1	1	1	6	6
Verification for supplements to petitions for stay of agency action (505(q)(1)(I)).	1	1	1	0.5 (30 min.)	0.5
Letter withdrawing a petition for stay of agency action	1	1	1	0.5 (30 min.)	0.5
Total Hours					35

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

Dated: September 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–23886 Filed 9–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0271]

Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice entitled ''Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Request for Comments,'' which appeared in the **Federal Register** of June 4, 2013 (78 FR 33421). The Agency is reopening the comment period in response to requests for additional time and to allow interested persons more time to submit comments.

DATES: Submit either electronic or written comments by October 31, 2013

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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 at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., HILL–3110, Silver Spring, MD 20993, 301–796–3603, FAX: 301–431–6351, *Nancy.sager@fda.hhs.gov;* Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Aaliyah Eaves-Leanos, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5435, 301–796–2948, FAX: 301–847–8510, *Aaliyah.Eaves-Leanos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 4, 2013 (78 FR 33421), FDA published a request for public comments from interested persons on the proposed availability of de-identified and masked data derived from medical product applications. In that notice, FDA requested comments by August 5, 2013, on the following topics: (1) What factors should be considered in masking study data (e.g., data fields from regulatory submissions to remove or modify, number of different products to pool within a product class); (2) what limitations, if any, should there be on the Agency's ability to make available the masked data as described previously; (3) are there any additional factors FDA should consider in de-identifying data in addition to FDA's requirement to remove any names and other information (e.g., birth date, death date, local geographic information, contact information) that would identify patients or research subjects before disclosing information; (4) would regulatory changes facilitate implementation of such a proposal, and if so, what changes would be most useful; and (5) which situations do you believe disclosing masked data would be most useful to advance public health?

The comment period was 60 days, but the Agency has received requests for an additional 30 days for submitting comments. Each request conveyed concern that the 60-day comment period did not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the requests and will reopen the comment period for an additional 30 days, thus extending the comment period to October 31, 2013. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*