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.*

Dated: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–23794 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–2011–D–0787]

Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' Through the approaches announced in this guidance, FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE regulations. Early feasibility studies allow for limited early clinical evaluations of devices to provide proof of principle and initial clinical safety data, often before the device design is finalized. This guidance addresses the information that should be provided to FDA in support of an early feasibility study IDE application and explains the requirements applicable to modifications to the device design or clinical study protocol during the early feasibility study.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dorothy Abel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1204, Silver Spring, MD 20993–0002, 301–796–6366; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is intended to provide assistance to FDA staff, clinicians, medical device innovators, and industry on the development and review of IDE applications (21 CFR 812.20) for early feasibility studies of significant risk devices. Early feasibility studies allow for early clinical evaluation of devices to provide proof of principle and initial clinical safety data in a limited number of subjects. During these studies, iterative device modifications are likely to be made based on clinical experience. Early feasibility studies may be appropriate early in device development when clinical experience is necessary because nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process. As with all clinical studies, initiation of an early feasibility study must be justified by an appropriate benefit/risk analysis and adequate human subject protection measures.

This guidance discusses the key principles unique to the justification for, and design of, early feasibility studies, and outlines the general principles for preparing and reviewing early feasibility study IDE applications. This guidance is not intended to address all required elements of an IDE application or to provide a comprehensive tutorial on best clinical practices for investigational medical device studies.

Concurrent with the publication of this guidance in draft, November 10, 2011 (76 FR 70150), FDA initiated a pilot program for early feasibility study IDE applications (November 10, 2011, 76 FR 70152) to solicit nominations from sponsors of innovative device technologies. In addition to making clarifications within the final guidance in response to comments from the public on the draft guidance, FDA has incorporated changes based on information learned and experiences gained from the pilot program.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on IDEs for Early Feasibility Medical Device Clinical Studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1782 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078;