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.

Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements—OMB Control Number 0910–0661—Extension

Under section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)), as amended by section 3052 of the 21st Century Cures Act (Pub. L. 114–255), FDA is authorized to exempt a humanitarian use device (HUD) from the effectiveness requirements in sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.,* for profit), except in narrow circumstances. Under section 520(m)(6)(A)(i) of the FD&C Act a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, provides that the Secretary of Health and Human Services will determine the ADN for devices that meet the eligibility criteria to be permitted to be sold for profit. The ADN is defined as the number of devices ''reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.''

Section 520(m)(6)(A)(iii) of the FD&C Act provides that an HDE holder immediately notify the Agency if the number of such devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

FDA is requesting the extension of OMB approval for the collection of information required under the statutory mandate of sections 515A (21 U.S.C. 360e–1) and 520(m) of the FD&C Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/section of FD&C Act, as amended by Food and Drug Administration Safety and Innovation Act (FDASIA) and 21st Century Cures Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act	1	1	1	100	100
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	1	1	1	50	50
Request for Determination of Eligibility Criteria—613(b) of FDASIA	1	1	1	10	10
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	1	1	1	100	100
Total					360

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

Our estimated burden for the information collection reflects a decrease in the number of responses and corresponding decrease of 1,010 hours in the total burden since our last OMB approval. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04450 Filed 3–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1113]

Data Integrity and Compliance With Drug Current Good Manufacturing Process: Questions and Answers; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Data Integrity and Compliance With Drug CGMP: Questions and Answers; Guidance for Industry; Availability'' that appeared in the **Federal Register** of December 13, 2018. The document announced the availability of a guidance for industry. The document was published with the incorrect docket number. This document corrects that error. Previously submitted comments will be transferred to the correct docket number.

FOR FURTHER INFORMATION CONTACT: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6686,

Silver Spring, MD 20993–0002, 301–796–3191.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, December 13, 2018 (83 FR 64132), in FR Doc. 2018–26957, the following correction is made:

On page 64132, in the first column, in the header of the document, ''[Docket No. FDA–2018–D–3984]'' is corrected to read ''[Docket No. FDA–2016–D–1113].''

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04431 Filed 3–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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, provisions of the notification procedure for substances generally recognized as safe (GRAS).

DATES: Submit either electronic or written comments on the collection of information by May 13, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 13, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–0021 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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,