the following topics: demographic information; HIV and STD risk behaviors; use of HIV and STD health services; experiences at school, including school connectedness, harassment and bullying, homophobia, support of Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) students; sexual orientation; receipt of referral for HIV and STD prevention health services; and health education.

This data collection system involves administration of a paper-and-pencil questionnaire to seven high schools that are participating in the HIV/STD prevention project of a local education agency that is funded with support from CDC's PS13–1308 cooperative agreement. The questionnaire, the Youth Health and School Climate Questionnaire, will be administered to approximately 16,500 students across the seven schools in the 2017–2018 school year. This is the third and final data collection of a four-year project that includes three data collections; previous data collections occurred in December 2014 and December 2016. Data collection points coincide with the approximate beginning, mid-way, and end points of the PS13–1308 cooperative agreement. We anticipate the final data collection will yield data from up to 16,500 high school students in grades 9 through 12 at the selected schools. Although some students may have completed the questionnaire in one or more of the previous years, this is not a longitudinal design and individual student responses will not be tracked across the years. No personally identifiable information will be collected.

All students' parents will receive parental consent forms that provide them with an opportunity to opt their children out of the study. In addition, each student will be read verbal assent language that explains he or she may choose not to take the questionnaire or may skip any questions in the questionnaire with no penalty. Participation is completely voluntary.

The estimated burden per response ranges from 35–45 minutes. This variation in burden is due to the slight variability in skip patterns that may occur with certain responses and variations in the reading speed of students. The burden estimate presented here is based on the assumption of a 40-minute response time per response. Students will complete the questionnaire only once under this approval. Annualizing the collection over one year results in an estimated annualized burden of 11,000 hours for respondents. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Students in grades 9–12 | Youth Health and School Climate Questionnaire. | 16,500 | 1 | 40/60 | 11,000 |
| Total | | | | | 11,000 |

**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. 2017–07482 Filed 4–12–17; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–4389]**

### Genome Editing in New Plant Varieties Used for Foods; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for a docket to receive information and comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We established the docket through a notice that appeared in the **Federal Register** of January 19, 2017. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** We are extending the comment period on the notice that published January 19, 2017 (82 FR 6564). Submit either electronic or written comments by June 19, 2017. Late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 19, 2017. 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.

**ADDRESSES:** You may submit comments 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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 2016–N–4389 for ''Genome Editing in New Plant Varieties Used for Foods.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management 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.'' We will review this copy, including the claimed confidential information, in our 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding human food issues:* Jason Dietz, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2282.

*Regarding animal food issues:* Kathleen Jones, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5938.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2017, we published a notice announcing the establishment of a docket to receive comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We requested these comments because we recognize that developers of new plant varieties, researchers, and other stakeholders may have valuable factual information and data about foods derived from new plant varieties produced using genome editing, which can help inform FDA's thinking for these specific products. The notice also discussed the history of FDA's thinking regarding these products, our long history of consultations with developers, researchers, and other stakeholders, and specific questions and issues for which we invited comments. We provided a 90-day comment period that was scheduled to end on April 19, 2017.

We have received requests for a 60-day extension of the comment period. The requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful comments to the questions and issues we presented in the notice.

We have considered the requests and are extending the comment period for 60 days, until June 19, 2017. A 60-day extension allows more time for interested persons to submit comments to the docket on this issue.

Dated: April 7, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–07469 Filed 4–12–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–1610]**

### Medical Devices; Exemptions From Premarket Notification: Class I Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has identified a list of class I devices that are now exempt from premarket notification requirements, subject to certain limitations. FDA is publishing this notice of that determination in accordance with procedures established by the 21st Century Cures Act. This notice represents FDA's final determination with respect to the class I devices included in this document. FDA's action will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulation.

**FOR FURTHER INFORMATION CONTACT:** Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, 301–348–1446, email: *Gregory.Bennett@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), and the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section