• 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

513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, part 807 of Title 21 of the Code of Federal Regulations (CFR), require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of that Act amended section 510(l) of the FD&C Act. As amended, section 510(l)(2) of the FD&C Act requires FDA to identify through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this determination within 120 days of the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Section 510(l)(2) further provides that upon the date of publication of the Agency's determination in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption. In a final action, FDA intends to amend the codified language for each listed classification regulation to reflect the final determination with respect to 510(k) exemption. 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. Specifically, regulated industry will no longer have to invest time and resources in 510(k) submissions for certain class I devices, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review.

II. Criteria for Exemption

As stated previously, section 3054 of the 21st Century Cures Act amended section 510(l) of the FD&C Act. In doing so, the amendments reorganized section 510(l) into subsections 510(l)(1) and (2). As such, subsection 510(l)(1) provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereafter ''reserved criteria''). Based on these reserved criteria, FDA has evaluated all class I devices to determine which device types should be exempt from premarket notification requirements. In developing the list of exempt devices, the Agency considered its experience in reviewing premarket notifications for these devices, focusing on the risk inherent with the device and the disease being treated or diagnosed (*e.g.,* devices with rapidly evolving technology or expansions of intended uses). The Agency also considered the history of adverse event reports under the medical device reporting program for these devices, as well as their history of product recalls. Following these considerations, FDA reached the final determination that the devices listed in table 1 do not meet the reserved criteria in that they are not intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury.

III. Limitations on Exemptions

FDA believes that the types of class I devices listed in this notice should be exempt from the premarket notification requirements found under section 510(k) of the FD&C Act. However, an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in this document is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

In addition to being subject to the general limitations to the exemptions found in 21 CFR 862.9, 864.9, 866.9, 872.9, 876.9, 878.9, 880.9, 882.9, 884.9 and 886.9, FDA may also partially limit the exemption from premarket notification requirements to specific devices within a listed device type. In table 1, for example, FDA lists the exemption of the ataxiagraph device as 510(k) exempt, but limits the exemption to such devices that do not provide an interpretation or a clinical implication of the measurement. All other ataxiagraph devices are still subject to premarket notification requirements because FDA determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices.

IV. List of Class I Devices

FDA is identifying the following list of class I devices that no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions:

TABLE 1—CLASS I DEVICES

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.1410	Bathophenanthroline, Colorimetry, Iron (Non-Heme)	CFM	
862.1410	Photometric Method, Iron (Non-Heme)	JIY	
862.1410	Atomic Absorption, Iron (Non-Heme)	JIZ	
862.1410	Radio-Labeled Iron Method, Iron (Non-Heme)	JJA	
862.1415	Ferrozine (Colorimetric) Iron Binding Capacity	JMO	
862.1415	Resin, Ion-Exchange, Thioglycolic Acid, Colorimetry, Iron Binding Capacity.	JQD	
862.1415	Resin, Ion-Exchange, Ascorbic Acid, Colorimetry, Iron Binding Capacity.	JQE	
862.1415	Bathophenanthroline, Iron Binding Capacity	JQF	
862.1415	Radiometric, Fe59, Iron Binding Capacity	JQG	

TABLE 1—CLASS I DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.1580	Phosphomolybdate (Colorimetric), Inorganic Phosphorus	CEO	
862.1660	Electrolyte Controls (Assayed and Unassayed)	JJR	
862.1660	Controls For Blood-Gases, (Assayed and Unassayed)	JJS	
862.1660	Enzyme Controls (Assayed and Unassayed)	JJT	
862.1660	Urinalysis Controls (Assayed and Unassayed)	JJW	
862.1660	Single (Specified) Analyte Controls (Assayed and Unassayed).	JJX	Exemption is limited to controls not intended for use in donor screening tests.
862.1660	Multi-Analyte Controls, All Kinds (Assayed)	JJY	Exemption is limited to controls not intended for use in donor screening tests.
862.1660	Tonometer (Calibration and Q.C. of Blood-Gas Instruments), Clinical.	LCH	
862.1660	Kit, Serological, Positive Control	MJX	Exemption is limited to controls not intended for use in donor screening tests.
862.1660	Kit, Serological, Negative Control	MJY	Exemption is limited to controls not intended for use in donor screening tests.
862.1660	Kit, Direct Antigen, Positive Control	MJZ	Exemption is limited to controls not intended for use in donor screening tests.
862.1660	Kit, Direct Antigen, Negative Control	MKA	Exemption is limited to controls not intended for use in donor screening tests.
862.1775	Acid, Uric, Phosphotungstate Reduction	CDH	
862.1775	Acid, Uric, Uricase (U.V.)	CDO	
862.1775	Acid, Uric, Uricase (Gasometric)	JHA	
862.1775	Acid, Uric, Uricase (Oxygen Rate)	JHC	
862.1775	Acid, Uric, Acid Reduction of Ferric Ion	LFQ	
862.3050	Devices, Breath Trapping, Alcohol	DJZ	
862.3220	Spectral Absorb. Curve, Oxyhemoglobin, Carboxyhemoglobin, Carbon-Monoxide.	JKS	
862.3220	Gas Chromatograph, Carbon-Monoxide	JKT	
862.3220	Enzyme Immunoassasy, Nocotine and Nicotine Metabolites.	MKU	
862.3240	Cholinesterase Test Paper	DIG	
862.3240	Colorimetry, Cholinesterase	DIH	
862.3240	Acetylcholine Chloride, Specific Reagent for Pseudo Cholinesterase.	DLI	
862.3240	Solution, M-Nitrophenol, Specific Reagent for Cholinesterase.	DMR	
862.3240	Electrometry, Cholinesterase	DOH	
862.3280	Heavy Metals Control Materials	DIE	
862.3280	Drug Mixture Control Materials	DIF	
862.3280	Digitoxin Control Serum, Ria	DJK	
862.3280	Alcohol Control Materials	DKC	
862.3280	Digoxin Control Serum, Ria	DMP	
862.3280	Drug Specific Control Materials	LAS	
862.3280	Theophylline Control Materials	LAW	
862.3280	Lidocaine Control Materials	LAX	
862.3280	Methotrexate Control Materials	LAY	
862.3280	N-Acetylprocainamide Control Materials	LAZ	
862.3280	Procainamide Control Materials	LBA	
864.7040	ATP Release (Luminescence)	JWR	
864.7040	Adenine Nucleotide Quantitation	KHF	
866.2900	Device, Parasite Concentration	LKS	
872.4565	Parallelometer	EGI	
872.4565	Syringe, Irrigating (Dental)	EIB	
876.5160	External Urethral Occluder, Urinary Incontinence-Control, Female.	MNG	
878.4014	Kit, First Aid, Talking	OVR	
880.5680	Pediatric Position Holder	PRN	
880.6250	Finger Cot	LZB	
880.6320	Device, Medical Examination, AC Powered	KZF	
880.6320	Accessories to Examination Light	PEQ	
880.6375	Lubricant, Patient	KMJ	
880.6760	Restraint, Patient, Conductive	BRT	
880.6760	Restraint, Protective	FMQ	
880.6760	Patient Bed with Canopy/Restraints	OYS	
882.1030	Ataxiagraph	GWW	Exemption is limited to ataxiagraph devices not intended to provide an interpretation or a clinical implication of the measurement.
882.4060	Cannula, Ventricular	HCD	
882.4545	Instrument, Shunt System Implantation	GYK	
884.5435	Pad, Menstrual, Reusable	NUQ	
884.5435	Pad, Interlabial	NUR	

TABLE 1—CLASS I DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
886.4070	Engine, Trephine, Accessories, Gas-powered	HLD	
886.4070	Burr, Corneal, Battery-powered	HOG	
886.4070	Engine, Trephine, Accessories, Battery-powered	HRF	
886.4070	Engine, Trephine, Accessories, AC-powered	HRG	
886.4070	Burr, Corneal, AC-powered	HQS	

Dated: April 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–07468 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–2008–D–0394]

Regulation of Intentionally Altered Genomic DNA in Animals; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance for industry (GFI) #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' that was announced 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 draft guidance published January 19, 2017 (82 FR 6561). Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance, submit either electronic or written comments on the draft guidance by June 19, 2017.

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–2008–D–0394 for ''Regulation of Intentionally Altered Genomic DNA in Animals.'' 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 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.'' 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 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: Laura R. Epstein, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–796–8558, *laura.epstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2017, FDA published a notice announcing the availability of draft GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' with a 90-day comment period. We requested comments on expanding the scope of the guidance to address animals intentionally altered through use of genome editing techniques, nomenclature, and on whether certain