indexing because they are not consumed by humans or by food-producing animals. Using the previous example of rabbits, this would mean a drug intended for use in laboratory rabbits could be eligible for indexing because this distinct population of rabbits is not intended to enter the human food chain. The stakeholders assert that because there is a reasonable certainty that laboratory rabbits will not be eaten, they should be considered to be non-food-producing for the purposes of indexing.

We want to optimize the incentives provided in the MUMS Act and support its intended purpose to increase legal drug availability for minor species. Changing current indexing policy for eligibility could help promote legal drug availability for underserved populations of animals; however, we do not intend to implement such a change if it might adversely affect human or animal health. The purpose of this notice is to give stakeholders the opportunity to provide feedback about this potential change to the current indexing policy for eligibility.

III. Request for Comments

We request comments, including response to the specific questions that follow, to assist in evaluating whether changing our current indexing policy for eligibility can increase the availability of safe and effective new animal drugs for use in some minor species while continuing to protect human and animal health.

Specifically, we request comment on the following:

1. What are the reasons we should or should not expand eligibility for indexing to certain discrete subsets of food-producing minor species?

2. If you support the expansion of indexing, please describe the information we should evaluate when determining which discrete subsets of food-producing minor species should be eligible.

3. Are there any discrete subsets of food-producing minor species that you believe should be eligible for indexing because they are not intended for consumption by humans or food-producing animals?

Dated: June 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13417 Filed 6–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3741]

Remanufacturing of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Remanufacturing of Medical Devices.'' This draft guidance is intended to help clarify whether activities performed on devices are likely ''remanufacturing.'' This draft guidance also includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 23, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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):* 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–2018–N–3741 for ''Remanufacturing of Medical Devices.'' 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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Remanufacturing of Medical Devices'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Katelyn Bittleman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4250, Silver Spring, MD 20993–0002, 240–402–1478; Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between ''servicing'' and ''remanufacturing.'' FDA has been working to gain additional perspectives on the distinction between ''servicing'' and ''remanufacturing'' and has undertaken several efforts to help promote clarity. FDA opened a docket for public comment (81 FR 11477) and held a public workshop (81 FR 46694) in 2016. Public comments submitted to this docket are searchable under FDA–2016–N–0436 (*https://www.regulations.gov/docket?D=FDA-2016-N-0436*).In 2018, FDA issued a white paper, opened a public docket, and held a public workshop to facilitate public discussion on the distinction between servicing and remanufacturing. Public comments submitted to this docket are searchable under FDA–2018–N–3741 (*https://www.regulations.gov/docket?D=FDA-2018-N-3741*). The white paper described FDA's initial thoughts about guiding principles, provided a flowchart with accompanying text for understanding the distinctions, and contained a complementary approach for software, as well as considerations for labeling, and examples utilizing the flowchart. FDA also included targeted questions throughout the white paper for which the Agency sought feedback. FDA concurrently opened a docket under FDA–2018–N–3741 and held a public workshop to discuss the white paper and obtain public comment before issuing draft guidance. FDA considered the comments from the public docket and discussions during the public workshop in developing this draft guidance.

Because of the apparent confusion between servicing and remanufacturing among entities performing these activities, FDA committed in the ''FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices'' (*https://www.fda.gov/media/113431/download*) to issue guidance that clarifies the difference between servicing and remanufacturing activities. To assist with this clarification, FDA focuses this draft guidance on those activities that are likely remanufacturing. The determination of whether the activities an entity performs are remanufacturing affects the applicability and enforcement of regulatory requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. FDA has consistently enforced requirements under the FD&C Act and its implementing regulations on entities engaged in remanufacturing, including but not limited to registration and listing, adverse event reporting, the Quality System regulation, and marketing submissions.

For activities involving components/parts/materials, FDA recommends the use of the flowchart in the draft guidance to help entities determine if their activities are likely remanufacturing. Although the servicing and remanufacturing definitions and guiding principles in this draft document apply to software, the flowchart should not be applied to changes involving software. FDA has instead identified several activities performed on software that are likely not remanufacturing. This draft guidance also includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life. This draft guidance is not intended to adopt significant policy changes, but to clarify FDA's current thinking on applicable definitions, and clarify, not change, the regulatory requirements applicable to remanufacturers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Remanufacturing of Medical Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products* or from the Center for Biologics Evaluation and Research at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Remanufacturing of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17048 and complete title to identify the guidance you are requesting.

III. Other Issues for Consideration

FDA's white paper introduced a flowchart that the Agency was considering proposing in draft guidance. FDA requested public comment on this flowchart during our December 2018

workshop and through the Docket No. FDA–2018–N–3741. While FDA has considered all comments and made changes as appropriate, FDA received opposing comments that suggested either no flowchart or more detail than FDA provided in the white paper. FDA encourages all interested stakeholders to comment on their preferred approach to help determine whether activities are remanufacturing and their rationale for such, using the following options: (1) No flowchart; (2) a flowchart similar to that proposed by FDA in this draft guidance; and (3) a more detailed flowchart, such as that proposed in comment FDA–2018–N–3741–0036.

IV. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and forms have been approved by OMB as listed in the following table:

21 CFR part; or FDA form	Topic	OMB control No.
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
807, subpart E	Premarket Notification	0910–0120
Form FDA 3670	Adverse Event Reports/MedSun program	0910–0471

Dated: June 15, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13360 Filed 6–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–1281]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZOLGENSMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZOLGENSMA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 23, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 21, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 August 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 23, 2021. 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–2020–E–1281 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZOLGENSMA.'' 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, 240–402–7500.

- 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