ANNUAL BURDEN ESTIMATES—Continued

| Instrument | Respondents | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Average burden per response (in hours) | Total burden (in hours) | Annual burden (in hours) |
|---|---|---|---|---|---|---|
| | Licensed LifeSet Experts<br>Provider Agency Administrators<br>LifeSet Developer Administrators | | | | | |
| Site Visit 2 Focus Group Guide for Staff. | LifeSet Specialists .....<br>LifeSet Team Supervisors | 12 | 1 | 1.5 | 18 | 6 |
| Baseline Youth Survey ..... | Youth Formerly in Foster Care. | 600 | 1 | 0.6 | 360 | 120 |
| Administrative data file ..... | Agency and Program Staff | 12 | 1 | 5 | 60 | 20 |

*Estimated Total Annual Burden Hours:* 160.

**Authority:** 42 U.S.C. 677.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2021–13468 Filed 6–23–21; 8:45 am]

**BILLING CODE 4184–25–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–2462]**

### Eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Request for Comments

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, we, or the Agency) is soliciting comments on our current policy on eligibility for indexing. Indexing is the process of adding an unapproved drug for a minor species to our index of legally marketed unapproved new animal drugs for minor species (the Index). Except for in some early non-food life stages, members of a food-producing minor species are not eligible for indexing, even if a subset of animals within a food-producing minor species is not intended to be consumed by humans or food-producing animals. Specifically, we are requesting comment on this policy.

**DATES:** Submit either electronic or written comments on the notice by September 22, 2021.

**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 September 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 22, 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–2017–D–2462 for ''Eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' 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 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.

**FOR FURTHER INFORMATION CONTACT:** Dorothy Bailey, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0565, *dorothy.bailey@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) (Pub. L. 108–282) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide incentives to develop new animal drugs for minor species and minor uses. By enacting the MUMS Act, Congress sought to encourage the development of animal drugs that are unavailable to minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) or to major species afflicted with uncommon diseases or conditions (minor use), while still ensuring appropriate safeguards for animal and human health. Congress recognized that the markets for drugs intended to treat these species, diseases, or conditions are too small to motivate animal drug companies to develop data to support drug approvals. Further, Congress recognized that some minor species populations have management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses.

One of the incentives established by the MUMS Act is the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (section 572 of the FD&C Act (21 U.S.C. 360ccc–1)). The final rule establishing administrative procedures and criteria for adding a new animal drug to the Index was published in the **Federal Register** on December 6, 2007 (72 FR 69108). The regulations are codified in Title 21, Code of Federal Regulations (CFR) part 516, subpart C.

We refer to the process of adding a new animal drug to the Index as ''indexing.'' Instead of using the new animal drug approval process, indexing is a faster and less expensive pathway to legal marketing of unapproved new animal drugs for use in some minor species. Adding a new animal drug to the Index uses a combination of FDA and qualified expert panel review. It is a three-step process with each step involving a submission from a requestor (the person making a request for determination of eligibility) and a review and decision by FDA. The three steps are as follows:

1. Requesting determination of eligibility for indexing (see 21 CFR 516.129);
2. Proposing a qualified expert panel to evaluate safety to the animal being treated (target animal safety) and effectiveness (see 21 CFR 516.141); and
3. Requesting addition to the Index (see 21 CFR 516.145).

As part of this process, FDA reviews information to support environmental safety, human user safety, manufacturing processes, and human food safety considerations. A qualified expert panel, once accepted by FDA, reviews information to support effectiveness and target animal safety of the new animal drug. The expert panel reviews all available information regarding target animal safety and effectiveness information, which can include study data, literature, and anecdotal information, to determine if the benefit of using the new animal drug outweighs the risk to the target animal. The expert panel must be unanimous that the benefit outweighs the risk for a drug to be added to the Index. FDA reviews the findings of the expert panel and the labeling for the new animal drug as part of the final submission. If we agree with the expert panel's conclusions, the drug is added to the Index found on our website at *https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species.* Once a drug is listed in the Index, the holder (the requestor of an index listing after a request is granted) is required to report to us any adverse events associated with use of the new animal drug. Extra-label use of an indexed drug is prohibited. This means a veterinarian or animal owner using an indexed drug can only do so legally by following label instructions.

Section 572(a)(1) of the FD&C Act states that the Index is limited to new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the FD&C Act (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance).

For the purposes of indexing, FDA's Guidance for Industry #210 entitled ''The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species'' [1] states that we consider a minor species to be a food-producing minor species when some members of the species are bred, cultured, farmed, ranched, hunted, caught, trapped, or otherwise harvested for the purpose of having the animals or edible products of the animals *commercially distributed* for consumption by humans or food-producing animals in the United States. When defining food-producing minor species for the indexing process, we adhered to current policy for new animal drug approvals regarding food-producing animals. For many years, we have considered an animal to be food-producing if any member of that species is raised to be food for humans. For example, some rabbits are raised to be used as food for humans; under current policy, including indexing policy, all rabbits, regardless of where they are housed, are considered to be food-producing. This means that a drug for use in laboratory rabbits is ineligible for indexing even though a rabbit raised for use in research is not intended to be consumed by humans or other food-producing animals.

## II. Stakeholder Feedback

We have received feedback from multiple animal stakeholder groups regarding the current indexing policy for eligibility. These stakeholders have asked us to allow indexing of drugs for use in certain populations of animals that would be considered food-producing under current indexing policy. Instead of considering any member of a food-producing minor species ineligible for indexing, they have requested that we establish criteria that, if met, could determine that a subset of animals within a food-producing minor species is eligible for

[1] Available at: *https://www.fda.gov/media/107583/download.*

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://*