(Rehabilitation Act), as amended by the Workforce Innovation and Opportunity Act (WIOA, Pub. L. 113–128), and the corresponding regulations at 45 CFR part 1329, require centers for independent living (CILs) to submit annual performance reports to the Administrator of the Administration for Community Living (ACL) in order to receive continuation funding under the IL Parts B and C programs.

The 704 reports are submitted annually by all Centers for Independent Living, designated State entities and Statewide Independent Living Councils receiving IL Parts B and C funds. The 704 Parts I and II reports are used by ACL to assess grantees' compliance with title VII of the Act, with section 1329 of the Code of Federal Regulations, and with applicable provisions of the HHS regulations at 45 CFR part 75. The 704 Parts I and II reports serve as the primary basis for ACL's monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The 704 Parts I and II reports also enable ACL to collect qualitative and quantitative data to track performance outcomes and efficiency measures of the IL programs with respect to the annual and long-term performance targets established in compliance with the GPRA Modernization Act of 2010 (GPRAMA) reporting requirements. The 704 Parts I and II reports are also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 721 of the Act.

Comments in Response to the 60-Day Federal Register Notice

A 60-day notice was published in the **Federal Register** in Vol. 82, No. 35, pg. 11471 on February 23rd, 2017. A Notice of Correction was published in the **Federal Register** in Vol. 82, No. 42 pg. 12610 on March 6th, 2017, announcing that ACL had made changes to the submission instructions, the public comments closing date was incorrect, the public comments email box was incorrect, and the core services were misstated in the original **Federal Register** posting ACL received comments from 50 (Fifty) organizations that provided 221 (Two Hundred and Twenty-One) individual comments about the proposed information collection. ACL reviewed all of the comments. The majority of the comments that ACL received expressed concerns over inclusion of sexual orientation and gender identity questions in the reporting instrument and asked that those questions be removed; the separate demographics and services provided to individuals with significant disabilities, and the need for clarification on the definitions and instructions as well as revisions to the IL core services and additional services sections of the updated reporting instrument. Further deliberation is needed to ensure that we appropriately address all of the concerns. This work will inform a redesign of the proposed information collection forms prior to the expiration of the extension.

Annual Burden Estimates

A copy of the existing Centers for Independent Living (CILs), designated State entities (DSEs) and Statewide Independent Living Councils (SILCs) Annual Performance Reports (704 Parts I and II reports can be found on ACL's Web site at: *https://www.acl.gov/about-acl/public-input.* The 704 Report's estimated hour burden per respondent each for the Part I (IL Part B) and Part II (IL Part C) in 2017 remains unchanged at 35 hours from 2014 because the current data collection instrument is the same as the one approved in 2014.

The total estimated hour burden also remains the same because the number of respondents, 412, has not changed since the 2014 approval.

The aggregate total hour burden for 412 Parts I and II 704 Report is estimated at 14,385, as follows:

Report	Number of DSEs and SILCs (Part B)	Frequency of responses per year	Average burden hours per response	Total annual burden hours
704 Report, Part I	55	1	35	1,925

Report	Number of IL Centers (Part C)	Frequency of responses per year	Average burden hours per response	Total annual burden hours
704 Report, Part II	356	1	35	12,460

Estimated Total Annual Burden Hours: 14,385.

Dated: September 11, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–19560 Filed 9–14–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2462]

The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species; Draft Guidance for Industry; 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 draft guidance for industry (GIF) #210 entitled ''The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' This draft guidance describes the process for adding a new animal drug to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). The Index consists of a list of legally marketed unapproved new animal drugs for minor species that meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by November 14, 2017 to ensure that the Agency considers your comments 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–2017–D–2462 for ''The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' 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.

- *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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dorothy Bailey, Center for Veterinary Medicine (HFV–50), 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 FD&C Act to provide animal drug companies with incentives to develop new animal drugs for minor species and minor uses in major species, while still ensuring appropriate safeguards for animal and human health.

One of the incentives established by the MUMS Act is the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, also referred to as ''the Index.'' The Index is available for new animal drugs intended for use in minor species; the Index is not available for drugs intended for minor use in major species (horses, cattle, pigs, turkeys, chickens, dogs, and cats).

The Index consists of a list of legally marketed unapproved new animal drugs for minor species that meet the requirements of section 572 of the FD&C Act (21 U.S.C. 360ccc–1). We refer to the process of adding a new animal drug to the Index as ''indexing.'' Indexing represents a pathway for legally marketing unapproved new animal drugs for minor species.

In the **Federal Register** of December 6, 2007, FDA published final regulations establishing administrative procedures and criteria for listing a new animal drug for use in a minor species in the Index (72 FR 69108). These regulations, which are codified at 21 CFR part 516, subpart C, are administered by the Office of Minor Use and Minor Species Animal Drug Development (OMUMS) within FDA's Center for Veterinary Medicine (CVM). That office also maintains the Index, which is available to the public through FDA's Web site at *http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125452.htm.*

FDA is announcing the availability of a draft GIF #210 entitled ''The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' This draft guidance describes the process for adding a new animal drug to the Index.

II. Significance of Guidance

This level 1 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 ''The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are

subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 516.119 through 516.165 have been approved under OMB control number 0910–0620.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: September 11, 2017.

Anna K. Abram,

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

[FR Doc. 2017–19609 Filed 9–14–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–4792]

Regulatory Considerations for Microneedling 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 ''Regulatory Considerations for Microneedling Devices—Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance is being issued to assist industry in understanding when a microneedling product is a device as defined in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). 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 November 14, 2017 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–2017–D–4792 for ''Regulatory Considerations for Microneedling Devices—Draft Guidance for Industry and Food and Drug Administration Staff.'' 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.

- 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.

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 ''Regulatory Considerations for Microneedling Devices—Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Peter Yang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1551, Silver Spring, MD 20993–0002, 301–796–6477.

SUPPLEMENTARY INFORMATION:

I. Background

''Microneedling products'' is a generic term that encompasses instruments with common technological features that include an array of needles, ''micro-protrusion'' tips, or pins, which can be