Caregivers Act of 2017 requires that the Secretary (of HHS) establish a process for public input to inform the development and updating of the Strategy, including a process to submit recommendations to the FCAC and provide public input on the same.

Family caregiving crosses racial, ethnic, socioeconomic, and cultural boundaries. It affects those in rural and urban settings and can span generations in a single household. A robust national strategy to support America's caregivers must take into consideration not only caregivers of older adults, but also those facing long-term care and respite care needs for those of any age resulting from any serious illnesses, conditions or disabilities. The strategy should also address the needs and considerations of caregivers of persons with Alzheimer's disease or a related dementia and people with intellectual or developmental disabilities.

**Public Input**

Through this RFI, ACL is seeking input from individuals and organizations that capture the breadth of the family caregiving experience. Specifically, we would like to learn from you based on your experience about challenges faced by family caregivers. In this regard, please keep in mind the following:

- All submissions will be considered and reviewed by the Family Caregiving Advisory Council.
- The Council seeks recommendations and actions to optimize solutions for family caregivers for inclusion in the National Strategy. (We may not be able to include all recommendations.)
- If you have multiple needs, concerns and/or recommendations, you may make multiple submissions.
- A *pressing family caregiving need or concern* is something you feel requires consideration for inclusion in the Strategy.
- A *recommendation* proposes a solution to the identified need/concern.
- A *challenge* is a categorization of the recommendation that may be, but not limited to: General, access, finance, health, and other. To the extent possible, please categorize your recommendation as follows: Greater adoption of person/family-centered care; assessment; service planning and/or delivery; care transitions/coordination; information, education, referral, training and advance planning; respite options; financial security; workplace issues; and/or other.

**Submission Questions**

1. A pressing family caregiving need/concern I would like to see addressed is:
2. I would like to offer this specific recommendation to address my need/concern: The recommendation addresses needed actions that pertain to:

**Please Note:** This RFI is being issued for information and planning purposes only. It should not be construed as a solicitation or an obligation on the part of the federal government or the Administration for Community Living (ACL). ACL does not intend to issue any grant or contract awards based on responses to this invitation, or to otherwise pay for the preparation of any information submitted or for the government's use of such information. ACL is not authorized to receive personally identifiable information (PII) through this RFI other than the contact information of the person submitting the information. Please do not include any PII in your submission. For example,F do not include names, addresses, phone or Social Security numbers of any individuals. We will immediately delete and not review responses that contain PII.

**How the Information Will Be Used**

ACL and the FCAC are planning for the Council's future activities, including the preparation of an Initial Report and the Family Caregiving Strategy. Additionally, ACL is developing a series of public listening sessions starting in calendar year 2020 as a way to engage with members of the public, families and family caregivers, stakeholders and other individuals and entities with an interest in understanding and supporting the multi-faceted needs of family caregivers across the age and disability spectrum. The information gathered through this RFI will be used to inform each of these activities and seek feedback from the public where/when appropriate.

**Background**

The RAISE Family Caregivers Act was signed into law on January 22, 2018. The RAISE Act requires the Secretary of HHS to promote improvement of the Federal, State, and community systems that support family caregivers. The two primary objectives of the RAISE Act are to:

1. Establish a national Family Caregiving Strategy with recommendations for ensuring person- and family-centered care, assessment and service planning, information on accessing hospice and palliative care, respite options, financial security and workplace issues, and delivering services in an effective and efficient manner; and
2. Establish a Family Caregiving Advisory Council of Federal and non-Federal representatives to provide recommendations and identify best practices to recognize and support family caregivers.

Public input is a key expectation of the RAISE Act. This RFI is the first opportunity for ACL to ensure that the activities and products of the FCAC are inclusive of and responsive to, the needs and expectations of a range of stakeholders with an interest in supporting family caregivers.

**How To Submit a Response to This RFI**

Comments should be submitted online at: *https://acl.gov/form/public-input-raise*.

**Submission Due Date**

To be assured consideration, all responses to this RFI must be received by 5:00 p.m., EST on February 7, 2020.

**For Further Information**

If you have questions about this request, please email them to *RAISEAct@acl.hhs.gov*. This is a resource mailbox established to receive public input for the RAISE Act, and should not be used to request information beyond the scope of this public input opportunity.

Dated: December 2, 2019.

**Lance Robertson,**

*Administrator and Assistant Secretary for Aging.*

[FR Doc. 2019–26438 Filed 12–6–19; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–1650]**

### Magnetic Resonance Coil—Performance Criteria for Safety and Performance Based Pathway; 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 ''Magnetic Resonance (MR) Coil—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidance identified in this notice was developed in accordance with the final guidance entitled ''Safety and Performance Based Pathway.'' 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 February 7, 2020 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–2019–D–1650 for ''Magnetic Resonance (MR) Coil—Performance Criteria for Safety and Performance Based Pathway; 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 ''Magnetic Resonance (MR) Coil—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff'' 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. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This draft device-specific guidance document provides performance criteria for premarket notification (510k) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' [1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the above-listed guidance, when finalized, rather than using direct predicate comparison testing for some of the performance characteristics.

## II. Significance of Guidance

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 performance criteria for the Safety and Performance Based Pathway for magnetic resonance coils. 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

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.*

it satisfies the requirements of the applicable statutes and regulations.

### III. 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.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Magnetic Resonance (MR) Coil—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19011)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

### IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA guidance have been approved by OMB as listed in the following table:

| 21 CFR part; guidance; or FDA form | Topic | OMB control No. |
|---|---|---|
| 807, subpart E | Premarket Notification | 0910–0120 |
| ''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''. | Q-Submissions | 0910–0756 |

Dated: December 3, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–26470 Filed 12–6–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–4433]**

## Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated With Internal or External Hemorrhoids; 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 a draft guidance for industry entitled ''Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated with Internal or External Hemorrhoids.'' This draft guidance will serve as a focus for continued discussions among the Division of Gastroenterology and Inborn Error Products, pharmaceutical sponsors, the academic community, and the public.

**DATES:** Submit either electronic or written comments on the draft guidance by February 7, 2020 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–2019–D–4433 for ''Development of Locally Applied Corticosteroid Products for the Short-Term Treatment of Symptoms Associated with Internal or External Hemorrhoids.'' 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