

total estimated hour burden per respondent for the proposed DD Council PPR will increase from the 138 hours

estimated in 2015 to 172 burden hours per response. The number of hours is multiplied by 56 State Council

programs, resulting in a total estimated hour aggregate burden of 9,632.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Councils on Developmental Disabilities/Program Performance Report	56	1	172	9632
Total	56	1	172	9632

Dated: June 7, 2018.  
**Lance Robertson,**  
*Administrator and Assistant Secretary for Aging.*  
 [FR Doc. 2018-12826 Filed 6-14-18; 8:45 am]  
**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Notice of Intent To Award a Single-Source Supplement**

**ACTION:** Intent To Award a Single-Source Supplement for the Amputee Coalition of America, Inc. for the National Limb Loss Resource Center Cooperative Agreement.

The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Amputee Coalition of America, Inc. for the National Limb Loss Resource Center (NLLRC). The purpose of this project is to expand on current grant activities, such as increasing activities and programs that promote health, wellness, and the adoption of healthy behaviors with the objective of preventing and/or reducing chronic conditions associated with limb loss and increase partnerships and collaborations with ACL programs that will benefit all people living with limb loss or limb differences. The administrative supplement for FY 2018 will be in the amount of \$669,905, bringing the total award for FY 2018 to \$3,697,142.

The additional funding will not be used to begin new projects. The funding will be used to enhance and expand existing programs that can serve an increased number of veterans and people living with limb loss and limb differences by providing increased technical assistance activities; promoting health and wellness programs; promoting the adoption of healthy behaviors with the objective of preventing and/or reducing chronic

conditions associated with limb loss; increasing partnerships and collaborations with ACL programs that will benefit all people living with limb loss or limb differences; enhancing and expanding the evaluation activities currently under way; and enhancing website capacities for improved information dissemination.

*Program Name:* National Limb Loss Resource Center.

*Recipient:* The Amputee Coalition of America, Inc.

*Period of Performance:* The supplement award will be issued for the third year of the three-year project period of April 1, 2016, through March 29, 2019.

*Total Award Amount:* \$669,905 in FY 2018.

*Award Type:* Cooperative Agreement Supplement.

*Statutory Authority:* This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b-4)); Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235 (Dec. 16, 2014).

*Basis for Award:* The Amputee Coalition of America, Inc. is currently funded to carry out the objectives of this program, entitled *The National Limb Loss Resource Center* for the period of April 1, 2016, through March 29, 2019. Since the program transferred from CDC to ACL in late 2015, the grantee has accomplished a great deal. The supplement will enable the grantee to carry their work even further, serving more people living with limb loss and/or limb differences and providing even more comprehensive training and technical assistance in the development of LTSS supportive services. The additional funding will not be used to begin new projects or activities. The NLLRC will enhance and expand currently funded activities such as conducting national outreach for the development and dissemination of patient education materials, programs, and services; providing technical support and assistance to community based limb loss support groups; and raising awareness about the limb loss and limb differences communities.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the people living with limb loss and limb differences currently being served by this program could be negatively impacted by a service disruption, thus posing the risk of not being able to find the right resources that could negatively impact on health and wellbeing. If this supplement were not provided, the project would be less able to address the significant unmet needs of additional limb loss survivors. Similarly, the project would be unable to expand its current technical assistance and training efforts in NLLRC concepts and approaches, let alone reach beyond traditional providers of services to this population to train more “mainstream” providers of disability services.

*For More Information Contact:* For further information or comments regarding this program supplement, contact Elizabeth Leef, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, Independent Living Administration: telephone (202) 475-2486; email [Elizabeth.leef@acl.hhs.gov](mailto:Elizabeth.leef@acl.hhs.gov).

Dated: June 6, 2018.  
**Lance Robertson,**  
*Administrator and Assistant Secretary for Aging.*  
 [FR Doc. 2018-12978 Filed 6-14-18; 8:45 am]  
**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-1788]

**Intravascular Catheters, Wires, and Delivery Systems With Lubricious Coatings—Labeling Considerations; 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 “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations.” This draft guidance addresses labeling considerations for devices containing lubricious coatings that are used in the vasculature. The purpose of this draft guidance is to provide recommendations for information to be included in device labeling, as submitted in premarket applications (PMAs) or premarket notification submissions (510(k)s) for class III and class II devices, to enhance the consistency of information across these product areas as well as to promote the safe use of these devices in clinical settings. 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 14, 2018 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–D–1788 for “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations.” 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 draft 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 “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations” 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:**

Leigh Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2656, Silver Spring, MD 20993–0002, 301–796–5613.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Hydrophilic- and/or hydrophobic-coated devices have been used for more than 20 years in minimally invasive diagnostic and therapeutic cerebrovascular, cardiovascular, and peripheral vascular procedures. Although these devices may offer patient benefits, evidence indicates that the coating may separate from intravascular devices in some circumstances. FDA has received and analyzed information concerning serious adverse events associated with hydrophilic and/or hydrophobic coatings separating (*e.g.*, peeling, flaking, shedding, delaminating, or sloughing off) from intravascular medical devices.

FDA has not concluded that any specific manufacturer or brand of these devices is associated with higher risks than others. The cause of coating separation is multifactorial, and can be associated with factors including device design, manufacturing, and use. Current FDA analysis suggests that use-related issues may be mitigated through proper device selection, preparation, and other labeling considerations that are addressed within this draft guidance.

This draft guidance addresses labeling considerations for devices containing lubricious coatings used in the vasculature. The purpose of this draft

guidance is to provide recommendations for information to be included in device labeling, as submitted in PMAs or 510(k)s for class III and class II devices, to enhance the consistency of coating information across these product areas as well as to promote the safe use of these devices in clinical settings.

## 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 "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations." 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. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This draft guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 16016 to identify the guidance you are requesting.

## IV. 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 part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 801 have

been approved under OMB control number 0910–0485.

Dated: June 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–12824 Filed 6–14–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–1775]

#### **Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling; 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 "Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling." This draft guidance provides recommendations for the information and testing that should be included in premarket submissions for guidewires intended for use in the coronary, peripheral, and neurovasculature. 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 14, 2018 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–D–1775 for "Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling." 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