Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 253 hours.

Total Annual Cost: None.

Needs and Uses: The information collection requirements contained under 47 CFR 73.1350(g) require licensees to submit a ''letter of notification'' to the FCC in Washington, DC, Attention: Audio Division (radio) or Video Division (television), Media Bureau, whenever a transmission system control point is established at a location other than at the main studio or transmitter within three days of the initial use of that point. The letter should include a list of all control points in use for clarity. This notification is not required if responsible station personnel can be contacted at the transmitter or studio site during hours of operation.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2023–09885 Filed 5–9–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

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

ACTION: Notice.

SUMMARY: 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).

FOR FURTHER 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, Office of Disability Services Innovation at (202) 475–2486 or *Elizabeth.leef@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this project is to expand on current grant activities occurring across communities. These activities include programs that promote independence, community living, and the adoption of healthy behaviors that promote wellness and prevent and/or reduce 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 2023 will be for $667,048 bringing the total award for FY 2023 to $4,065,215.

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; addressing healthcare access issues, including maternity care; 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 fifth year of the five-year project period of April 1, 2019, through March 29, 2024.

Total Supplement Award Amount: $667,048 in FY 2023.

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, 2019, through March 29, 2024. Almost 2 million Americans have experienced amputations or were born with limb difference and another 28 million people in our country are at risk for amputation. 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 long-term 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.

Dated: May 4, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–09910 Filed 5–9–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1661]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 9, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0814. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

Sometimes called ''compassionate use,'' expanded access (EA) is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Agency regulations in 21 CFR part 312 provide for individual patient EA and associated procedures for those submitting EA requests to FDA. We provide resource information on our website at *https://www.fda.gov/news-events/public-health-focus/expanded-access* regarding our EA program, including information for patients, physicians, and industry. We also provide information pertaining to forms and processes for submitting EA requests to FDA. Specifically, we have developed electronic Form FDA 3926 ''Individual Patient Expanded Access Investigational New Drug Application (IND).'' Upon accessing the online form, users may need to follow certain technical instructions to save the document in a portable document format (PDF). Form FDA 3926 requires the completion of data fields that enable FDA to uniformly collect the minimum information necessary from licensed physicians who want to request EA as prescribed in the applicable regulations.

Description of Respondents: Respondents to the collection of information are licensed physicians who request individual patient access to investigational drugs.

In the **Federal Register** of December 14, 2021 (86 FR 71069), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. However, on our own initiative, we are proposing the following revisions to associated Form FDA 3926:

TABLE 1—SUMMARY OF PROPOSED DATA FIELD CHANGES TO FORM FDA 3926

Current field:	Includes proposed changes to:	Becoming new field:	With accompanying instruction to:
8. Physician Name, Address, and Contact Information.	Delete ''Physician's IND number, if known'' from this field and move to proposed Field 4.a. Add ''Name of Institution or Clinical Practice'' to the title of the field.	1. Physician Name, Name of Institution or Clinical Practice, Address, and Contact Information. Remaining fields become renumbered.	Enter the physician's name, name of institution or clinical practice, and the physician's contact information, including the physical address, email address, telephone number, and facsimile (FAX) number.
3.a. Initial Submission.	Add ''enter the Physician's IND Number, if previously issued by FDA,''.	4.a. Initial Submission ..... ☐ Select this box if this form is an initial submission for an individual patient expanded access IND, enter the Physician's IND Number, if previously issued by FDA, and complete only fields 5 through 8, and fields 10 and 11.	If the submission is an initial (original) submission for an individual patient expanded access IND (including for emergency use), select the box provided in field 4.a., enter the physician's IND number, if previously issued by FDA, and complete only fields 5 through 8, and fields 10 and 11. Do not include commercial sponsor's IND number.
4. Clinical Information. Brief Clinical History (Patient's age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options).	Add ''or sensitivities, race and ethnicity (optional)'' after allergies. Add ''Ethnicity (check one)'' and list choice options (Hispanic/Latino or Not Hispanic/Latino). Add ''Race (check all that apply)'' and list choice options (American Indian/Alaska Native or Asian or Black/African American or Native Hawaiian/Other Pacific Islander or White).	5. Clinical Information ..... Brief Clinical History (Patient's age, gender, weight, allergies or sensitivities, race and ethnicity (optional), diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options). Ethnicity (check one) ☐ Hispanic/Latino ☐ Not Hispanic/Latino Race (check all that apply) ☐ American Indian/Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian/Other Pacific Islander ☐ White	Provide the indication (proposed treatment use) and a brief clinical history of the patient. The clinical history includes age, gender, weight, allergies or sensitivities (general (*e.g.,* soy) and drug specific) and other optional demographic and clinical information (*e.g.,* race (as reported by the patient; you may choose multiple answers) and ethnicity (choose only one response)), diagnosis (*e.g.,* a brief summary (with dates) of relevant past medical and surgical history, diagnostic procedures, current stage/severity of disease, and functional status), prior therapy, response to prior therapy (*e.g.,* patient was treated with drug X and subsequently developed lung metastasis), and the reason for requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options (*e.g.,* patient has failed or is intolerant to currently available therapy, or is not eligible for any clinical trials registered at *ClinicalTrials.gov*).

TABLE 1—SUMMARY OF PROPOSED DATA FIELD CHANGES TO FORM FDA 3926—Continued

Current field:	Includes proposed changes to:	Becoming new field:	With accompanying instruction to:
5: Treatment Information.	Add ''(including rationale for dose)''. Add ''(*e.g.,* assessment criteria/procedure(s) for monitoring and frequency)''. Add ''(*e.g.,* criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment),''. Add ''(*e.g.,* concomitant medication)''. Add ''You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed.''.	Field 6	Provide treatment information, including the investigational drug's name and the name of the entity supplying the drug (generally the manufacturer), the applicable FDA review division (if known), and a concise statement regarding the treatment plan. This includes the planned dose, route and schedule of administration of the investigational drug (including rationale for dose), planned duration of treatment, monitoring procedures (*e.g.,* assessment criteria/procedure(s) for monitoring and frequency), planned modifications to the treatment plan in the event of toxicity (*e.g.,* criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment), and other relevant information (*e.g.,* concomitant medication). The information should be entered within the space provided. You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed.
None	Add a box option for ''Request for Withdrawal'' under ''Summary of Expanded Access Use (treatment completed)''.	9. Contents of Submission ..... ☐ Request for Withdrawal.	Field 9: Contents of Submission (Follow-up/Additional Submissions Only). *Request for Withdrawal:* A submission describing the intent to withdraw an effective IND (21 CFR 312.38).
None	Add ''When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted.''.	Field 10.b.: Request for Authorization to Use Alternative IRB Review Procedures.	Select this box to request under 21 CFR 56.105, authorization to obtain concurrence by the IRB chairperson or by a designated IRB member, instead of at a convened IRB meeting, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted.
None	Add ''Information on where and how to submit this form is available at Expanded Access—How to Submit''.	Field 11: Certification Statement and Signature of the Physician.	Field 11: Certification Statement and Signature of the Physician Information on where and how to submit this form is available at Expanded Access—How to Submit.
[General Instruction?].	Insert a statement ''Information on where and how to submit this form is available at Expanded Access—How to Submit a Request (Forms)'' under ''Signature of Physician'' after Field 11.	[General Instruction?]	Information on where and how to submit this form is available at Expanded Access—How to Submit a Request (Forms).

We retain the currently approved burden estimate of 13,910 responses and 255,326 hours annually for the information collection. We anticipate no adjustment as a result of the proposed form updates and have posted a draft of revised Form FDA 3926 to the docket, available for public inspection through *https://www.regulations.gov.*

Dated: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09982 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–0675]

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

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 Detectnet 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by July 10, 2023. 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 November 6, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late,