I. Background

FDA is announcing the availability of a draft leapfrog guidance for industry and FDA staff entitled ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' The intent of this draft guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices, with careful considerations of regulatory least burdensome principles, as well as, ethical principles in animal testing. This draft guidance provides clarity on premarket recommendations to develop animal transplant models for organ preservation technologies, which will streamline initiation of clinical studies. Optimizing animal and clinical study designs for premarket submissions will allow us to bring novel organ preservation devices to the market faster to increase the availability of organs for transplant for patients awaiting transplants. Early stakeholder feedback was sought to inform the development of this draft guidance through CDRH's notice on the fiscal year 2016 proposed guidance development issued December 29, 2015 (80 FR 81335), available at *https://www.federalregister.gov/documents/2015/12/29/2015-32726/medical-device-user-fee-and-modernization-act-notice-to-public-of-web-site-location-of-fiscal-year#h-14.* Specific questions were posed to solicit input into the context of the guidance and comments were collected through Docket No. FDA–2012–N–1021.

This draft guidance is a leapfrog guidance; leapfrog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development. This leapfrog draft guidance represents the Agency's initial thinking, and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with CDRH through the Pre-Submission process to obtain more detailed feedback regarding their organ preservation device. For more information on Pre-Submissions, please see ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' at (*https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf*).

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).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 ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' 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 guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Utilizing Animal Studies to Evaluate Organ Preservation Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500083 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance document refers to previously approved collections of information found in FDA regulations and guidances. 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 58 regarding good laboratory practices have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485. The collections of information in 21 CFR part 807, subpart E regarding premarket notification have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 regarding investigational device exemptions have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814, subparts A through E regarding premarket approval have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in 21 CFR part 820 regarding the Quality System regulation have been approved under OMB control number 0910–0073. The collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: September 6, 2017.

Anna K. Abram,

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

[FR Doc. 2017–19613 Filed 9–14–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Poison Help General Population Survey, OMB No. 0915–0343, Reinstatement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. The ICR is for reinstatement with change of a previously approved information collection assigned OMB control number 0915–0343 that expired on May 31, 2014. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 16, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer, Lisa Wright-Solomon, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Poison Help General Population Survey OMB Number 0915–0343, Reinstatement.

Abstract: HRSA is requesting approval by OMB for reinstatement with change of a previously approved collection of information (OMB control number 0915–0343). Annually, poison control centers (PCCs) in the U.S. manage approximately 2.8 million calls, providing ready and direct access to vital public health emergency information and response. In 2001, the Poison Help line, a single, national toll-free phone number (800–222–1222) was established to ensure universal access to PCC services, 24 hours a day, 7 days a week. The Poison Help campaign is the only national media effort to promote awareness and use of the national toll-free phone number.

The Poison Help campaign aims to reach a wide audience, as individuals of all ages are at risk for poisoning and may need to access PCC services. The ''Poison Help General Population Survey'' is a 10-minute telephone survey designed to assess the campaign's impact among 2,000 households in the United States. The survey is conducted with an adult household member and addresses topics related to the types of individuals or organizations to contact for information, advice, and treatment related to a poisoning.

Need and Proposed Use of the Information: Survey results will be used to guide future communication, education, and outreach efforts and will allow the tracking of longitudinal data from near-identical prior surveys conducted in 2008 and 2011. The survey has been updated to include questions regarding one of the Secretary of HHS' priority areas, addressing the opioid crisis, and to definitively ascertain respondents' knowledge of the Poison Help Line and phone usage.

Likely Respondents: This study includes two respondent groups, individuals and households with an adult member 18 years and older.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Survey Respondents	2000	1	2000	.166	332
Screened households	2600	1	2600	.016	41.6
Total	4600		4600		374

Amy McNulty.

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–19608 Filed 9–14–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: Government owned intellectual property covering imaging agents with improved renal clearance available for licensing and commercialization.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology available for licensing follows.

Methods of Using Inhibitors To Enhance Therapeutic Uses of Endocannabinoids

Description of Technology: The invention pertains to methods of using compounds that inhibit fatty acid amide hydrolase (FAAH) enzymes that are responsible for the degradation of oleamide and anandamide. Inhibition of degradation can be used as treatment modality for hypertension and for sleep disorders. The issued patent lists potentially useful compounds, one such useful compound in particular is