

this applicant seeks 1,186 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12829 Filed 5–31–16; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

OpenFDA Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: OpenFDA Public Workshop. The purpose of the public workshop is to provide a forum for the openFDA system user community to engage in a robust interactive discussion and provide feedback to FDA regarding openFDA's platform, application programming interfaces (APIs), downloadable harmonized datasets, and possible enhancements to the openFDA platform, as well as to view the demonstration of various applications (apps) specifically developed for utilization of openFDA data.

DATES: The public workshop will be held on June 20, 2016, from 9 a.m. to 12 p.m. See the **SUPPLEMENTARY**

INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 (The Great Room 1503A), Silver Spring, MD 20993. For information regarding ground transportation, airports, lodging, driving, and parking, please refer to: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT:

Lonnie Smith, Office of Health Informatics, Office of Chief Scientist, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8503, email: lonnie.smith@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: OpenFDA, an FDA Office of Health Informatics initiative launched in June 2014, is making it easier for researchers, scientists, web developers, and other FDA regulatory stakeholders to access and use datasets in an open standard format.

The project aims to create easy access to public data and a new level of openness and accountability, ensure the privacy and security of public FDA data, educate the public, and save lives.

Members of the scientific community can use openFDA to have their applications automatically query the data through APIs. OpenFDA increases the efficiency and speed of accessing datasets by using cutting-edge, open-source code modules in a cloud-based environment.

Requests for openFDA app demonstrations: This public workshop includes demonstrations of mobile apps specifically developed for utilization of openFDA data. During registration you may indicate if you wish to provide a demonstration of an app which you have created that utilizes openFDA data. FDA will do its best to accommodate requests to demonstrate openFDA-based apps. The openFDA app demonstrations should not include any presentation slides and, due to FDA internet firewall restrictions, will be limited to only information and displays accessible via apps which can be accessed via internet

browsers Internet Explorer version 11 and Firefox versions 6 or higher. All requests to make app demonstrations must be received by 5 p.m., June 6, 2016. FDA will determine the amount of time allotted to each presenter and the approximate time each app demonstration is to begin, and will select and notify participants by 5 p.m., June 10, 2016. If selected for an app demonstration, any demonstration materials must be emailed to Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) no later than 5 p.m., June 16, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Registration: There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this workshop must register by sending the attendee's full name and email address via email message to openFDA@fda.hhs.gov before June 10, 2016. For those without Internet access, please contact Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) to register.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register by 4 p.m., June 10, 2016. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after June 10, 2016.

If you need special accommodations due to a disability, please contact Lonnie Smith (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12826 Filed 5–31–16; 8:45 am]

BILLING CODE 4164–01–P