

under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subpart B for PMAs have been approved under OMB control number 0910–0231.

Dated: January 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1255]

Electronic Submission Process for Requesting Export Certificates From the Center for Devices and Radiological Health; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an electronic submission process for requesting export certificates for products regulated by FDA's Center for Devices and Radiological Health (CDRH). The electronic process will help fulfill both the legislative and application time processing requirements set out by the FDA Export Reform and Enhancement Act of 1996 and the terms of clearance of the Office of Management and Budget approval (OMB control number 0910–0498) of the Form FDA 3613 series. The new eSubmitter process will complement the current paper-based process.

FOR FURTHER INFORMATION CONTACT:

Leila Lawrence, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2668, Silver Spring, MD 20993–0002, 301–796–5786, email: Leila.Lawrence@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. How eSubmitter Impacts FDA's Current Process

FDA currently accepts requests for export certificates submitted by mail. This process will remain in place and would be augmented by the new eSubmitter process.

For general user assistance, contact the Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by telephone: 1–800–638–2041 or 301–796–7100; or by email: dsmica@fda.hhs.gov.

You can find information about FDA's Electronic Submissions Gateway online at: <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>. Email questions about the system to FDA's Electronic Submissions Gateway Help Desk: esgreg@gnsi.com.

II. Background on the Electronic Submission of Requests for Export Certificates

FDA introduces an electronic option for submitting requests for export certificates of devices regulated by CDRH as a voluntary alternative to paper submissions. With electronic submissions, CDRH can more readily receive and process the export requests.

The electronic process will be introduced in two phases. In the first phase of operation, the CDRH Export Certification Application and Tracking System (CECATS) will be made available to industry for the electronic submission of requests for export certificates.

CECATS is a Web-based application used by FDA's CDRH to process, manage, and administer certificates for the export of medical devices. CDRH will be implementing the electronic submission and review process. Industry will have an option to submit electronically or via the paper process. CECATS will be accessible through the FDA Unified Registration and Listing System (FURLS). A firm must have a FURLS account to access CECATS.

The CECATS module is a part of the FURLS application within the FDA Industry Systems Portal utilized to automatically issue the certificate to U.S. medical device manufacturers/distributors who wish to export their medical devices to foreign countries.

CECATS will help fulfill both the legislative and application time processing requirements set out by the FDA Export Reform and Enhancement Act of 1996 (Public Law 104–134) and the terms of clearance of the OMB approval of the Form FDA 3613 series.

CECATS will provide industry the option of submitting export requests electronically. Electronic submission will automate many of the steps that both industry and CDRH must perform to submit and process export certificates. The advantages to industry will be:

- Certificate processing time will be greatly reduced;
- Automated real-time validation will eliminate the need to return submissions; and
- Industry will receive real-time updates on the status of their requests via the Web.

In early 2013, FDA will implement phase two for the remainder of the export certification, notification, and permit requests listed as follows:

- Certificates of Exportability (sections 801(e)(1) and 802 of the FD&C Act);
- Non-Clinical Research Use Only Certificate;
- Simple Notifications (section 802(g) of the FD&C Act); and
- Export Permit Letter (section 801(e)(2) of the FD&C Act).

Upon full implementation in 2013, industry will be able to submit all export requests electronically. This is a “win” for both industry and CDRH as it will allow us to process all export requests more efficiently and expeditiously. CDRH is developing webinars and will hold online training sessions with industry on how to access and use CECATS. A schedule and detailed instructions will be sent to industry and posted to our Web site at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050521.htm#ref> when they become available.

Evaluation of the electronic submission process will be conducted periodically to further enhance both user interface and data collection needs as they become known to FDA. Electronic submissions of requests for export certificates will remain voluntary at this time.

The printable forms can be viewed at the following links:

- Form FDA 3613: Supplementary Information Certificate for Foreign Government Requests: <http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012794.pdf>;
- Form FDA 3613a: Supplementary Information Certificate of Exportability Requests: <http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012795.pdf>;
- Form FDA 3613c: Supplementary Information Non-Clinical Research Use Only Certificate: <http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012797.pdf>.

III. What happens when the new eSubmitter process for requesting export certificates is implemented?

Implementation of the eSubmitter process will supplement the ability to request export certificates from CDRH via paper. The new Web-based application (available at: <https://www.access.fda.gov/oaa/index.jsp>) uses your existing FURLS account

information. The Web site provides an alternative to the paper request process by enabling online submission of export certificate applications.

IV. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in CECATS and Forms FDA 3613, 3613a, and 3613c have been approved under OMB control number 0910–0498.

Dated: January 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cardiovascular Sciences.

Date: February 7–8, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, nussb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–10–244, Structure and Function of Opioid Receptors.

Date: February 11–12, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David R. Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435–1722, jollieda@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Biomedical Imaging and Engineering Area Review.

Date: February 12, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301–435–1049, lij21@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group, Hypertension and Microcirculation Study Section.

Date: February 14, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Dallas Marriott Suites Medical—Market Center, 2493 North Stemmons Freeway, Dallas, TX 75207.

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, zouai@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Bacterial Pathogenesis Study Section.

Date: February 19, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard G Kostriken, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–402–4454, kostrkr@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group, Molecular and Cellular Hematology Study Section.

Date: February 19–20, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6183, MSC 7804, Bethesda, MD 20892, 301–495–1213, espinozala@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Integrative Neuroscience.

Date: February 19, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nicholas Gaiano, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892–7844, 301–435–1033, gaianonr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Nanotechnology and Molecular Substrates in Brain and Retinal Disorders.

Date: February 19, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Yvonne Bennett, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, bennetty@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 15, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monographs for 1-Bromopropane and Cumene; Availability of Documents; Request for Comments; Notice of Meeting

SUMMARY: Peer review meeting of the Draft Report on Carcinogens (RoC) Monographs for 1-Bromopropane and Cumene. These documents were prepared by the Office of the Report on Carcinogens (ORoC), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS).

DATES: Meeting: March 21, 2013, 1:00 p.m. to approximately 5:00 p.m. Eastern Daylight Time (EDT) and March 22, 2013, from 8:30 a.m. until adjournment, approximately 2:00 p.m. EDT.

Document Availability: Draft monographs will be available by January