

access. FSMA did not change the required information for cancellations. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

We estimate that the new biennial registration required by FSMA, which will require the submission of certain new data elements and the verification and possible updating of other information rather than re-entering all information, will require 30 minutes (0.5 hour) per response, including time for the new FSMA-required information. FDA estimates that, on an annualized basis, the number of biennial registrations submitted over the next 3 years will be 224,930. This estimate is based on the number of currently registered firms (449,860) divided by two. Thus, the total annual burden for biennial registration is estimated to be 112,465 hours (224,930 x 0.5 hours).

Dated: January 16, 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-D-1240]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Submissions for Postapproval Modifications to a Combination Product Approved Under Certain Marketing Applications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." This draft guidance intends to provide the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product that is approved under one marketing application, i.e., a biologics license application (BLA), a new drug application (NDA), or a device premarket approval application (PMA).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft

guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 22, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your request. The draft guidance may also be obtained by mail by calling the Office of Combination Products at 301-796-8930. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Patricia Y. Love, Office of Combination Products, Food and Drug Administration, Bldg. 32, rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." This document provides guidance to industry and FDA staff on the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product, as defined in 21 CFR 3.2(e), that is approved under one marketing application, i.e., a BLA, an NDA, or a device PMA.

The regulatory standards for when to provide a postmarket submission for a change to an approved, stand-alone drug, device, or biological product or its manufacturing process are described in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 505, 506A, and 515 of the FD&C Act), the Public Health Service Act (PHS Act) (section 351 of the PHS Act), and FDA's associated regulations (21 CFR 314.70, 601.12, and 814.39). As a general matter, these provisions set forth similar criteria for when a submission for a changed article is required, but do not expressly address submissions for changes to an approved combination product.

This draft guidance intends to provide clarity in the postapproval change

requirements and consistency in the type of postmarket submission to provide for a change to a combination product approved under one marketing application (BLA, NDA, or PMA). In particular, the draft guidance document provides tables that may be helpful in determining what type of submission to provide for a postmarket change to a constituent part of a combination product where the regulatory identity of the modified constituent part differs from the application type under which the combination product is approved.

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 Agency's current thinking on "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Comments**

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

##### **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 314 for NDAs have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 for BLAs have been approved

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](mailto: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](mailto: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@gsni.com](mailto:esgreg@gsni.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