

Exporting Medical Devices

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Hello, my name is Tonya Wilbon. I am the Branch Chief for the Postmarket and Consumer Branch within the Division of Industry and Consumer Education. Welcome to CDRH Learn, the Center's resource for multimedia industry education. The title of this presentation is "Exporting Medical Devices" and it will provide some helpful information about exporting medical devices, regulated by the United States Food and Drug Administration, or U.S. FDA.

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Manufacturers commercially distribute medical devices in the U.S as well as other countries. When exporting these devices outside of the U.S., manufacturers are often asked by foreign governments to provide written certification that the devices to be exported into their country meet U.S. FDA regulations and laws or can be marketed in the U.S.

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In today's presentation, I will discuss general export requirements under the FDA Export Reform and Enhancement Act of 1996. I will refer to this law as the Export Act for the rest of the presentation. The learning objectives are to, first, review background information about the CDRH Exports Program. Next, describe the purpose of the export documents. Third, identify the different types of certificates and criteria for each. Then, describe what is an Export Permit Letter and a Simple Notification. Next, explain the steps to request export documents. Finally, I will explain the recordkeeping requirements for the different types of export documents.

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As I mentioned, foreign governments often ask for information about the regulatory status of devices entering their country.

What's often confused by establishments is the need to provide notice to or obtain approval by FDA before they're allowed to export their medical devices. If a medical device is legally marketed in the U.S., then it may be exported anywhere in the world without prior FDA notification or approval.

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The Export Act authorizes FDA to certify the regulatory and marketing status of medical devices being exported. Specifically, it authorizes FDA to issue export certificates and to approve or deny a request for a certificate. It also authorizes medical device manufacturers to request a certificate for the devices they export.

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In addition, the Export Act authorizes FDA to charge a fee for certificates issued within 20 working days. It modified Section 801 of the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and actually replaced Section 802.

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Foreign governments often seek official assurance that products exported to their countries meet specific criteria. Depending on the type of export document issued, the document may certify that the establishment is compliant with the FD&C Act and conforms to current good manufacturing practices

based on the most recent inspection history of the establishment. The export documents may also certify that the devices may be legally marketed in the U.S.

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Export certificates for medical devices are issued, approved, or denied by the Center for Devices and Radiological Health, or CDRH. CDRH issues four types of Export Certificates. They are: Certificate to Foreign Government, or CFG; Certificates of Exportability under Sections 801(e) and 802 of the FD&C Act; and Non-Clinical Research Use Only Certificate. CFGs account for over 95% of the thousands of requests received by CDRH each year.

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Classification of the device must be known when making a request for export certification. A list of medical devices with their associated classifications may be found in the Product Classification Database on the FDA Medical Device website embedded as a hyperlink in this slide. FDA establishment registration and device listing are both required for some medical devices prior to receiving a certificate. Certificates issued by CDRH are printed on special security paper to reduce the possibility of fraud. As stated on the certificates, they are valid for two years from the date the certificate is issued. The certificates are individually numbered and bear the signature of an authorized CDRH individual.

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Let's continue with the 4 types of certificates. Certificate to Foreign Government, or CFG, is issued for devices that are legally marketed devices in the U.S. These are devices that may be Class I, II, or III, or exempt by regulation. Establishments are registered, and the devices are listed with FDA as required.

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A CFG is issued for devices that meet any applicable labeling requirements. The establishment must have no open recalls for the devices listed on the certificate. If there are any open recalls, the firm will be asked to sign a special statement as part of the certification process indicating the firm will not ship any devices covered by that open recall. To receive a CFG, the establishment must comply with the Quality System Regulation of Title 21 Code of Federal Regulations Part 820, or 21 CFR 820, unless exempt by regulation. The establishment must also comply with the laws of the importing country.

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A Certificate of Exportability under Section 801(e)(1) is issued for devices that are NOT legally marketed in the U.S. and are either Class I, II, or are exempt by regulation. The establishments are required to be registered with FDA and devices may be listed.

The establishments must also comply with the laws of the importing country and meets specification of foreign purchaser. The devices must be labeled on the outside of the shipping package as "intended for export".

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CDRH also issues a Certificate of Exportability under Section 802. This certificate is issued for devices that meet performance standards per Section 514 of the FD&C Act, specifically for Class II or III devices that are not legally marketed. Establishments are required to be registered with FDA. The devices must also be listed and meet the specifications of the foreign purchaser.

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In addition, the establishments must comply with the laws of the importing country. The devices are marketed in the countries listed in Section 802(b)(1)(A)(i) and (ii) of the FD&C Act. Certificate of Exportability under Section 802 is also issued for devices under investigational use in those same countries. The devices must be labeled on the outside of the shipping package as “intended for export”.

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The devices must not be adulterated and the establishment must substantially conform to current good manufacturing practices (CGMPs). Reimportation of the device must not pose an imminent hazard to the U.S. or the country receiving the device.

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Finally, Non-Clinical Research Use Only certificates are issued for a product, material, or component intended for non-clinical research use only and NOT human use. The devices are marketed in, and legally exported from the U.S. as required by the FD&C Act.

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In addition to issuing export certificates, CDRH issues an Export Permit Letter per Section 801(e)(2) and receives a Simple Notification per Section 802(g). I will review these over the next few slides.

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Export Permit Letters are not certificates. FDA will require an Export Permit Letter before a device may be exported, if it meets certain criteria. The device must be Class III, investigational, made according to the specifications of the foreign purchaser, not conflict with the laws of the country intended for export, and not be approved for marketing in the U.S.

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The Export Permit Letter is issued for devices that are labeled on the outside shipping package as “intended for export”. These devices are banned per Section 516 of the FD&C Act and are not in compliance with Section 514 for lack of complying with performance standards. A CGMP inspection is not required for issuance of the letter.

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Export Permit Letters are also issued for devices that are unapproved, that is, either a Premarket Approval Application (PMA) was not submitted to FDA or FDA did not approve the PMA. They are issued for devices that do not meet the criteria for exporting under Section 802 . Export Permit Letters are issued for those devices not authorized for marketing in a country listed in Section 802(b)(1)(A)(i) and (ii) as well as investigational devices not authorized in those countries.

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FDA does not charge a fee for issuing the Export Permit Letter and is not required to issue the letter within 20 days.

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An unapproved device intended for investigational use may be exported under Section 802(c) of the FD&C Act without FDA authorization. If an export document is needed, an Export Permit Letter would be the document issued. The investigational device must be exported to any country listed in Section 802(b)(1)(A)(i) and (ii) and comply with the laws of that country. The investigational devices being

exported are not required to meet the Investigational Device Exemption (IDE) regulation requirements of 21 CFR 812. Exportation of these devices to any country other than those listed must be authorized.

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When you export the first initial shipment of a device to a country, you must provide FDA with written notification per Section 802. This written notification is considered a “Simple Notification”. A certificate is not issued. FDA will issue an Acknowledgement Letter. A Simple Notification does not require FDA approval and no fee is charged. FDA is not required to issue this Acknowledgment Letter within 20 days.

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As required by 21 CFR 1.101(d), a Simple Notification must identify the product’s trade name, type of device, the product’s model number, and the country to receive the exported product if the country is not listed in Section 802(b)(1) .

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In addition, if exporting to a country listed in Section 802(b)(1)(A), the Simple Notification must identify that country or indicate that the export is intended for a country that is listed without identifying the listed country.

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To submit a request for export documents, you must first register your establishment with FDA using the FDA Online Account Administration, or FDA OAA. The website is hyperlinked on this slide. An FDA OAA account ID and password will be provided after you register. You should use this account ID and password to access the CDRH Export Certification and Tracking System, or CECATS. and to create subaccounts for affiliate establishments.

CECATS may be accessed after logging into the FDA Unified Registration and Listing Systems (FURLS). Requests for the specific export document can then be submitted using CECATS. The CECATS system offers several benefits, including a reduction in certificate processing time, real-time validation of firm-specific data, and status updates for the request. We highly recommend submitting requests electronically.

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This slide provides some of the information required to request an export document or to submit a Simple Notification. These include: registration or owner operator number of all the establishments involved with the manufacturing of the device, the marketing authorization number and dates product was granted to market, and the Federal Tax ID number of the individual making the request.

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Additional information you may need to submit your request electronically also includes: the FDA recall number and the date the recall was closed. This is to be submitted for any device included in the request. Also provide the total number of certificates needed and the list of countries for which the certificate is being requested.

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Please contact CDRH Export Staff regarding submitting a hard copy request using the contact information on this slide.

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Currently, the fee is \$175.00 for the first certificate and \$85.00 for each subsequent certificate from the same request. Do not submit payment with the request. There is no fee for Export Permit Letters and Simple Notifications. If the certificate is issued within 20 days, CDRH will bill you on a quarterly basis.

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Each Export Certificate is limited to 25 pages. If printing goes beyond the 25 pages, an additional \$175 fee will be assessed. There is no limit to the number of copies that can be requested.

The name of foreign firms can appear on the Export Certificate. If you want individual countries to be listed on the certificate, a separate application is required. If CDRH needs additional information, you will be contacted often by a return for action email. Please respond within the requested 48 hours. If you do not provide the information within this timeframe, your request will be returned unfulfilled.

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Firms exporting a product under Section 801(e)(1) must maintain records demonstrating that the product meets specified requirements according to 21 CFR 1.101(b). Records must be retained for the same period of time as required by 21 CFR 820.180, for the expected life of the device, but not less than 2 years from the date of release for commercial distribution by the manufacturer. The records must be made available to the FDA, upon request, during an inspection for review and copy by the FDA.

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Recordkeeping requirements for exporting under Section 802 include the recordkeeping requirements for exporting under 801(e)(1) according to 21 CFR 1.101(g). In addition to those requirements, establishments are required to keep records that include the product's trade name, the type of device, the product's model number, the consignee's name and address, and the date on which the product was exported, and the quantity exported. It is important that you maintain these records.

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Additional recordkeeping requirements for exporting devices under Section 802 are also included on this slide and include keeping records at the site from which the products were exported or manufactured.

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After viewing this presentation, I hope you have a better understanding of the requirements for exporting medical devices regulated by the FDA. In summary, legally marketed devices in the U.S. may be exported without prior FDA notification. CDRH will only issue export certificates for medical devices. Remember, requests submitted using CECATS are processed faster. And finally, CDRH also issues permit letters and receives simple notifications for exporting devices.

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As your call to action, I encourage you to register all facilities listed on the export document request and make sure you respond to CDRH as directed within 48 hours regarding additional information about your export request.

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We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory questions, please contact CDRH's Division of

Industry and Consumer Education using the information provided on this slide. We look forward to helping you. Thank you for watching this program.

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