Draft Screenshots and Instructions for Form FDA 3613l

Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a written export certification for products regulated by the U.S. Food and Drug Administration (FDA). FDA has developed a draft electronic form, Form FDA 3613g, for firms that wish to request export certificates pursuant to section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Form FDA 3613l will be part of the Certificate Application Process (CAP), which a web-based application through which FDA receives, processes, and tracks applications for export certification.

The screens below depict the process through which industry users may apply for export certification issued pursuant to section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act for most food products. Please note that there are separate processes for applying for different types of export certificates.

Contents

Screen #1: Select Enter New Application

To submit a new application, select the link 'Enter New Application' from the page 'CAP Home Main Menu'. Note: The OMB control number and expiration date will be updated upon OMB approval.

Screen #2: Select Product Type and Certificate Type

Applicants will first be prompted to identify the product type and the certificate type.

Screen #3: Section 1 – Requestor Information

In Section 1, Requestor Information will be autopopulated from the applicant's FDA Industry Systems account information. Applicants may indicate if the requestor information is the same as the billing information, and if not, they will be prompted to provide billing information.

Screen #4: Section 2 – Manufacturer Information and other optional facility selection for Certificate Display

Next, applicants will be asked to identify the manufacturing facility for the products that will be listed on the certificate. Applicants will also have the option to identify exporter, distributor, and consignor. Applicants can choose up to two companies to be listed on the certificate.

Screen #5: Section 2 – Facility Identifier Information, Select Identifier

Applicants may enter the DUNS number, FEI number, or Food Facility Registration information to identify the manufacturer and other companies.

Screen #6: Section 2 – Confirm Name and Address Information

Name and address information will be prepopulated based on the FDA records for the facility.

Screen #7: Section 3 – Certificate Information

Next, applicants will be prompted to identify the country of destination for the shipment and the number of certificates requested for each country. All certificates associated with a particular application will include the same product and shipment information; only the country name and the unique ID for the certificate will vary.

Screen #8: Section 4.1 – Shipment Information

Section 4.1 will allow the applicant to provide product information for the products that will be listed on the certificate. Certain fields will be required depending on the product type.

Screen #9: Section 4.2 – Review Product Details

After entering all the product information for the first product, applicants will be able to review the product list, edit product information and labels, and add additional products. In addition, the applicant will be able to select multiple headers that can be showed on the certificate such as the value of the good(s), unit of measurement, the scientific name of the product(s), etc. If there are multiple products in an application, headers can only be selected if both products have information entered for the desired header.

Screen #10: Section 4.3 – Additional Information

Applicants will have the option to add additional shipment details or upload additional documents as may be required by the importing country.

Screen #11: Section 5 – Signature Page

Screen 11 displays the signature page that will be required for submission. Note: The signature text varies depending on the type of certificate requested.

Screen #12: Application Review

After entering all the information, applicants will be able to review the complete application and preview the certificate before submission.

Screen #13: Confirmation Page

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