Online Applications for Export Lists

Launch the

FDA Industry System's Export Listing Module (ELM) (http://www.access.fda.gov/)

OMB Approval Numbers: 0910-0509 OMB Expiration Dates: 07/31/2022

Download Step-by-Step Instructions (PDF: 5.3MB) (/media/112092/download)

Tips for Submitting ELM Applications for Products Subject to China's Decree 248

Tips for submitting ELM applications for products subject to China's Decree 248 include the following:

- Applicants may look up the FDA Establishment Identifier (FEI) for their establishments in the FEI Search Portal (https://www.accessdata.fda.gov/scripts/feiportal/index.cfm? action=portal.login).
- For establishments that have not been inspected by FDA, please upload a copy of the most recent state inspection report to the ELM application. You can use the FEI number to search the FDA Data Dashboards (https://datadashboard.fda.gov/ora/fd/fser.htm) to confirm whether FDA has inspected a particular establishment. If you need help finding an FEI, you can contact the Export Certification Team at CFSANExportCertification@fda.hhs.gov (mailto:CFSANExportCertification@fda.hhs.gov).
- If the establishment is routinely inspected by the U.S. Department of Agriculture (USDA), please provide the USDA plant number in the Plant Identifier field.
- In the ELM, when submitting product information, establishments should provide the product name and Schedule B/HTS number to the 8- or 10-digit level. Establishments must also include the date of the last consignment for at least one product on the application.

General Tips for Completing an ELM Application

When submitting an ELM application, you will be asked to identify the facility for listing in one of four ways: using the Food Facility Registration, the FEI number, the DUNS number, or the certificate number from the Interstate Certified Shellfish Shippers List (ICSSL). (https://www.cfsanappsexternal.fda.gov/scripts/shellfish/sh/shellfish.cfm). The ELM will autopopulate your name and address for listing from FDA records based on the way that you identify the facility. Please note: Shellfish shippers must use their ICSSL number. For all other firms, the best option is to use the Food Facility Registration, which allows you to have complete control over the name and address that gets populated on your ELM application. The second-best option is to use your FEI number.

Important Information about Approval Numbers for Export Lists

All importing countries/regions with export list requirements ask FDA to provide an "approval number" to uniquely identify each facility on the list. The importing countries/regions usually require that this approval number appear on the labeling or packaging of exported products and the export certificate that accompanies each shipment. When an application is approved in the ELM, the system will send an email notification to the contact listed on the application that includes the approval number for the firm. FDA's general policy is to use the 10-digit FEI (FDA Establishment Identifier) number as the approval number on export lists; please review the sections below for information about specific export lists.

Any firm may request to be listed with a different approval number or request to change their existing approval number by uploading a letter to their ELM application that includes the firm's name, address, current approval number, and the desired approval number. Please review the approval number on the email notification from the ELM and contact the <u>CFSAN Export Certification Team</u>

(mailto:CFSANExportCertification@fda.hhs.gov) immediately if you have any concerns.

• Important Information about EU Requirements for Vessels

The EU now requires registration certificates for all vessels. In the ELM, vessel applicants should upload a valid vessel registration certificate from NOAA or the U.S. Coast Guard in the Additional Documents section.

Specific Information on Shellfish Firms

For shellfish firms that appear on the <u>Interstate Certified Shellfish Shippers List</u> (https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list) (ICSSL), FDA's general policy is to use shellfish certification numbers as approval numbers for the EU shellfish export list. FDA intends to use a standard format for the certification numbers assigned by state or local shellfish control authorities: the two-letter state abbreviation, hyphen, the 1-5 digit certificate number, hyphen, the two-

letter activity symbol, hyphen, and the two-letter permit designation symbol (if multiple, separated by commas). The use of this standard format (ST-0001-SS-PHP) is intended to facilitate the use of existing certification numbers as the approval numbers for the EU shellfish export list. Please note that the approval number on the EU list must match the number on the product labels or tags and the number of the export certificate. Any firm may upload a letter to their ELM application if they wish to use a different approval number.

For firms that intend to export processed shellfish products and are not listed on the ICSSL, FDA's general policy is to use the 10-digit FEI number as the approval number for the EU shellfish export list.

• Specific Information on Seafood Firms

FDA's general policy is to use the 10-digit FEI number as the approval number for the seafood export lists. However, there are many establishments that are currently included on seafood export lists with the 7-digit CFN as the approval number. FDA no longer uses CFNs internally, but there is no need to change these approval numbers for currently-listed establishments.

When you first submit an ELM application, the ELM will automatically assign the FEI for the establishment as the approval number. If you are currently listed with another approval number, FDA will replace the automatically-assigned approval number with your current approval number. Due to name and address changes, it's not always possible for us to match up an ELM application with a currently-listed establishment, so please review the email notification from the ELM when your application is approved to confirm that we have assigned the correct approval number. If you have any questions about approval numbers, please contact CFSANExportCertification@fda.hhs.gov).

• Using the Food Facility Registration in ELM

If you choose to identify the facility using the Food Facility Registration (FFR), the ELM will display a list of all registered food facilities associated with your FDA Industry Systems (FIS) account. If your account is only associated with one registered food facility, the system will automatically select that facility and move to the next screen.

If you represent a food facility but do not see an option in the ELM to identify the facility by the FFR, you can associate this facility with your account using the facility's FFR number and PIN. To do this, click on the "Food Facility Registration" link from the FIS home page. Once the Food Facility Registration system opens, select "Link Registration to your Account" on the left side of the screen and enter the facility's Food Facility Registration number and PIN. When you log back into the ELM, you should have access to this facility.

Once you have selected the facility for the application, you will be able to choose any name on the FFR as the "Name for Listing." If you do not see the name with which you would like to be listed in the dropdown, you can save your ELM application as a draft, log in to the Food Facility Registration system, add the name with which you would like to be listed in the "Alternate Trade Names" section, and then go back to the ELM to complete your application.

The ELM will pull the facility address from the FFR as the address for listing. If this address is incorrect, you can save your ELM application as a draft, log in to the Food Facility Registration system, correct the facility address, and then go back to the ELM to complete your application.

If you have any trouble completing your application or would like to submit your applicating in writing, please contact <u>CFSANExportCertification@fda.hhs.gov</u> (<u>mailto:CFSANExportCertification@fda.hhs.gov</u>).