Step-by-Step Instructions for the Export Listing Module (ELM)

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Accessing the Export Listing Module (ELM)

Figure 1: Creating an FDA Industry Systems Account

The Export Listing Module (ELM) is an FDA Industry System (FIS) and can be accessed via https://www.access.fda.gov/. If you do not have an existing FIS account, click on the “Create New Account” button to create one. This will take you to the Create New Account screen where you may select the center and the systems you will need to access.

NOTE: You may wish to create a single enterprise account for all FDA submissions related to your facility and to create subaccounts for personnel that will manage submissions to FDA. All submissions by subaccounts will be accessible via the enterprise FIS account, which will allow continued access to previous submissions in the event that an employee leaves the facility. For more information on account management, please visit review the FDA Industry Systems User Guide: Account Management.
On the Create New Account screen, under the Registration and Listing Programs select Export Listing Module as one of the systems you will need to access. You may select additional systems if you wish. If you need detailed instructions for creating a new account, please visit Create New Account Step-by-Step Instructions. Once you have created an account and logged in, you will see the online account administration page for FDA Industry Systems.
To access the Export Listing Module, log in to the FDA Industry Systems. Under Registration and Listing Programs, select Export Listing Module (ELM).
Figure 4: Welcome to the Export Listing Module (ELM)

After clicking on the ELM, you will reach the Export Listing Module welcome page. The menu on the left side of the screen provides the following options: Enter New Application, Edit Application, and Biennial Update.
Edit Application

Figure 5: ELM Edit Application Dashboard

To view a list of the applications associated with your account, select “Edit Application” from the menu on the left side of the screen. You may search for applications by entering key words in the filter text box or by using the sort button in each category column.

- Select the eye icon in the action column to view the application.
- Select the pencil icon in the action column to edit the application. This will allow you to change any editable fields in the application.
- Select the red "X" button to request to delete an application. Please note that if you delete an application with an Application Status of “Approved”, it will be removed from the export list.
Enter New Application

Figure 6: Product and Country/Region

To request to be added to an export list, select “Enter New Application” from the menu on the left side of the screen. You will be prompted to identify the Product Type and Country/Region of the export list for which you wish to apply. After making your selection, click the blue “Next” button at the bottom of the screen to proceed with the application.
Figure 7: Facility Information

You may identify the facility for listing by entering a DUNS number, a FDA Establishment Identifier (FEI), or by selecting a food facility associated with your FIS/OAA account.

You may visit https://fdadunslookup.com/ to search for or request a valid DUNS number.

If you represent a food facility, but do not see an option to identify this facility by the Food Facility Registration, you may associate this facility with your account if you have the facility’s Food Facility Registration number and PIN. To do this, click on the “Food Facility Registration” link from the FURLS/FIS home page. Once the Food Facility Registration module 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.
If you choose to identify the facility for listing by the Food Facility Registration, the system will display a list of all registered food facilities associated with your OAA account. Select the correct facility for your application and click the blue “Next” button at the bottom of the screen to proceed with the application.
If you choose to identify the manufacturer by FEI number, enter the FEI number and click the blue “Next” button at the bottom of the screen to proceed with the application.
If you choose to identify the manufacturer by DUNS number, enter the DUNS number and click Next. If there are multiple facilities associated with the DUNS number, you will have the option to select the correct name and address.

You may visit https://fdadunslookup.com/ to search for or request a valid DUNS number.
Figure 7.4: DUNS Facility Information

After you enter the DUNS number, you can select which manufacturing facility you wish to identify for this application. Only manufactures associated with your OAA login account will be displayed. If you enter a DUNS number that is not associated you will be able to manually enter the facility information. Click the blue "Next" button at the bottom of the screen to proceed with the application.
Figure 8: Existing Application Error

The system will not allow you to submit a duplicate application for a facility for the same product type and country/region. You will see an error message if you try to select a facility for which there is already an application for the product type and country/region.
After you have identified the facility, the Business Information page will display. If you identified the facility using a Food Facility Registration, this section is prepopulated from the Parent Company section of the Food Facility Registration (FFR) module. If you identified the facility using an FEI number or a DUNS number, this section is not prepopulated and you may optionally enter this information. The Doing Business As field is optional.
The Main Contact Information is prepopulated from the your FDA Industry Systems Account. If you need to edit this information, you may return to the FURLS Home Page and select “Edit Account Profile.” Notifications about this application will be sent to this email address.
Please confirm the name and address with which you wish to be listed in the “Facility Information for Listing” section. Select the facility type from the dropdown menu. If there are multiple facility names associated with the FDA records for your facility, you will be able to select a name from the “Name for Listing” dropdown menu.

If you identified the facility using a Food Facility Registration, this section is prepopulated from the Facility section of the Food Facility Registration (FFR) module. If you want to edit any information in the Facility Information for Listing section, you must first update the information in your FFR accordingly.

If you identified the facility using an FEI or a DUNS number, this section is prepopulated from FDA databases based on the FEI or DUNS entered. If you want to edit any information in the Facility Information for Listing section, please contact the FDA division where the facility is located to update the FDA records for the facility.

The Inspection Details section is optional. You may enter your plant identifier, select the last type of inspection that was conducted at the manufacturer’s facility. Enter the date the inspection was completed and upload an inspection notice (i.e., report of inspection findings).

Select the “Browse” button to upload an inspection notice. You may attach a document in jpeg., jpg, doc., docx., txt., xls., xlsx., pdf., gif., and rtf format. After you have selected the document, click the “Upload” button. If the document was successfully uploaded, you will see a confirmation message. Select the “Next” button to move forward in the application.
You may upload additional documents for review. To upload additional documents, select the browse button. You may attach a document in jpg., jpeg., doc., docx., txt., xls., xlsx., pdf., gif., and rtf format. After you have selected the document, click the “Upload” button. You will see a confirmation message if the document was successfully uploaded.

For firms exporting to China, you may upload evidence of a third-party audit here.

For Collagen and Gelatin applications, you may upload your laboratory results here. Establishments must provide a laboratory report from an accredited, private laboratory demonstrating that the products for export do not exceed the following criteria:

- Total aerobic bacteria –103/g
- Coliforms (30°C) - 0/g
- Coliforms (44.5°C) - 0/10g
- Anaerobic sulphite-reducing bacteria (no gas production) -10 /g
- Clostridium perfringens - 0/g
- Staphylococcus aureus - 0/g
- Salmonella - 0/25g
- As - 1 ppm
- Pb - 5 ppm
- Cd - 0,5 ppm
- Hg - 0,15 ppm
- Cr - 10 ppm
- Cu - 30 ppm
- Zn - 50 ppm
- SO2 - 50 ppm
- H2O2 - 10 ppm
You may identify an additional contact to receive updates about the application. If you do not wish to identify an additional contact, select the “Autofill Main Contact Information” button. Select “Next” to proceed with the application.
Product Information
The fields on the product information screen will vary depending on the product type and country/region selected.

Figure 14: Dairy EU Product Information

Please enter all required information. Select “Next” to proceed with application.
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Figure 15: Dairy China Product Information
Product Information

<table>
<thead>
<tr>
<th>Country</th>
<th>China</th>
<th>Product Type</th>
<th>Dairy</th>
</tr>
</thead>
</table>

Animal Origin
Product Category
Product Name (Optional)
Schedule BHTS Number
Value of Goods (Optional)
Quantity (Optional)
Unit of Measure
Is this product currently being manufactured and ready to ship?

Please enter all required information. Select “Next” to proceed with application.
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Figure 16: Dairy Chile Product Information

Please enter all required information. Select “Next” to proceed with application.
Step-by-Step Instructions for the ELM

Figure 17: Seafood China Product Information

Please enter all required information. Select “Next” to proceed with application.
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Figure 18: Seafood EU Product Information

Please enter all required information. Select “Next” to proceed with application.
Figure 19: Infant Formula China Product Information

Product Information

<table>
<thead>
<tr>
<th>Country</th>
<th>China</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Instant Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Origin</td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td></td>
</tr>
<tr>
<td>Schedule BHTS Number</td>
<td></td>
</tr>
<tr>
<td>INF Number</td>
<td></td>
</tr>
<tr>
<td>Infant Formula Type</td>
<td></td>
</tr>
<tr>
<td>Value of Goods (Optional)</td>
<td></td>
</tr>
<tr>
<td>Quantity (Optional)</td>
<td></td>
</tr>
<tr>
<td>Unit of Measure</td>
<td></td>
</tr>
<tr>
<td>Is this product currently being manufactured and ready to ship?</td>
<td></td>
</tr>
</tbody>
</table>

Please enter all required information. Select “Next” to proceed with application.
Figure 20: Collagen EU Product Information

Please enter all required information. Select “Next” to proceed with application.
Figure 20.1: Fish Collagen EU Product Information

Product Information

<table>
<thead>
<tr>
<th>Country</th>
<th>European Union (EU)</th>
<th>Product Type</th>
<th>Collagen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Fish</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please enter all required information. Select “Next” to proceed with application.
Please enter all required information. Select “Next” to proceed with application.
Figure 21.1: Fish Gelatin EU Product Information

Product Information

<table>
<thead>
<tr>
<th>Country</th>
<th>European Union (EU)</th>
<th>Product Type</th>
<th>Gelatin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Fish</td>
<td></td>
</tr>
</tbody>
</table>

- Animal Origin:
- Product:
- Schedule HS Number:
- Value of Goods (Optional):
- Quantity (Optional):
- Unit of Measure:
- Aquaculture Product:
- Is this product shipping within the next two years?

Please enter all required information. Select “Next” to proceed with application.
The Product List page will display the product associated with the application. Select the Next button to proceed with the application. To add additional products to your application, select the “+Add Product” button.
The application review page will display all entered information. You may revise each section by selecting the edit button. After reviewing, select the “Next” button to proceed with the application.
Enter all required fields on the Signature Page. Select the “Submit” button to submit the application for processing.
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Figure 25: Confirmation Page

After submission, a confirmation page will display your application number. Please keep this number for future inquiries about your application.
Biennial Update

Figure 26: Biennial Update

To view all applications that require an update, select “Biennial Update” from the menu on the left side of the screen. You will be prompted to select a country/area.

Figure 27: Biennial Update List of Applications

The system will display all applications for the selected country/area. Select the radio button for the application for which you wish to submit a biennial update and click the blue “Reapply” button to continue. Confirm the information on each page of the application before submitting.