Step-by-Step Instructions for the Export Listing Module



The Export Listing Module (ELM) is an electronic system for receiving and processing requests from FDAregulated establishments that wish to be included on export lists for FDA-regulated food products.

The information provided in the ELM is used to generate export list updates for the importing countries that require these lists. It is the establishment's responsibility to ensure that the establishment and products for export are identified correctly on the application. It is very important that the names and addresses of establishments on export lists reflect the records in FDA's Official Establishment Inventory.

Once listed, an establishment may edit their ELM application at any time to request an update to their listing information. All establishments are required to update and resubmit their ELM applications every two years to verify their listing information and indicate that they wish to continue being listed. Establishments that do not update and resubmit their ELM applications every two years will be removed from the lists. To ensure that the establishment receives reminder notifications prior to an application's expiration date, please list two contacts with accurate information for each application.

For assistance at any time, please contact the CFSAN Export Certification Team at <u>CFSANExportCertification@fda.hhs.gov</u> or 240-402-2307.

Contents

Accessing the Export Listing Module (ELM)	2
Navigating the ELM Dashboard	6
Submitting or Editing an Application	8
Appendix A: Using the Food Facility Registration in ELM	42
Appendix B: Email Notifications from the ELM	43
Appendix C: Product, Country, and Facility Type Matrix	44

Accessing the Export Listing Module (ELM)

Figure 1: Creating an FDA Industry Systems Account

FDA Industry Sy	stems			C	Check System Status
			o the U.S. Food and Drug Adr a week, since October 16, 20		ig registrations, listings,
	1	> Log-In	+ Create Account		
supply. The Act requires that	t FDA develop two system the United States and one	ns: one to support the to receive prior notic	gave high priority to improve registration of facilities that m to before food is imported or o went into effect.	nanufacture, process, pack	, or hold food products
supply. The Act requires that intended for consumption in	t FDA develop two system the United States and one	ns: one to support the to receive prior notic	registration of facilities that m be before food is imported or o	nanufacture, process, pack	, or hold food products
supply. The Act requires that intended for consumption in law, facilities must be regist	It FDA develop two system the United States and one ered by December 12, 200 cld Canned Foods 2541f/2541g	Is: one to support the e to receive prior notic 13 when Prior Notice w FURLS Biologics E	registration of facilities that m the before food is imported or of went into effect. Export Certification kking System (BECATS)	Anufacture, process, pack offered for import into the U FURLS Export Listin Form 3972 (07/18) OMB Approval Numb	, or hold food products Inited States. Under the ng Module (ELM) er 0910-0509
supply. The Act requires the intended for consumption in law, facilities must be regist Systems Index FURLS Acidified/Low Act (LACF) Form 2541/2541e/	It FDA develop two system the United States and one erred by December 12, 200 cld Canned Foods 25411/2541g 110-0037	s: one to support the to receive prior notic 3 when Prior Notice w FURLS Biologics E Application & Trac Form 3613 (05/18)	registration of facilities that m se before food is imported or over went into effect. Export Certification kking System (BECATS) liber 0910-0498	FURLS Export Listin FURLS Export Listin Form 3972 (07/18) OMB Approval Numb OMB Exploration Date See OMB Burden Sta	or hold food products inited States. Under the ng Module (ELM) er 0910-0509 07/31/2022 itement.
supply. The Act requires the intended for consumption in law, facilities must be regist Systems Index FURLS Acidified/Low Ac (LACF) Form 2541/2541e/ OMB Approval Number 0	If FDA develop two system the United States and one pred by December 12, 200 ild Canned Foods 2541fi2541g 110-0037 11/2020	Is: one to support the to receive prior notic 3 when Prior Notice w FURLS Biologics E Application & Trac Form 3613 (05/18) OMB Approval Num	registration of facilities that m we before food is imported or of went into effect. Export Certification king System (BECATS) hiber 0910-0498 te 04/30/2021	FURLS Export Listin Form 3972 (07/18) OMB Approval Numb OMB Approval Numb	, or hold food products Inited States. Under the ng Module (ELM) er 0910-0509 07/31/2022

The Export Listing Module (ELM) is one of the FDA Industry Systems (FIS) and can be accessed via <u>https://www.access.fda.gov</u>. Click the "Log-In" button to log in using an existing FIS account or click the "Create Account" button to create a new FIS account.

NOTE: Every account created from the FIS home page is an "enterprise" account and each enterprise account can create subaccounts to allow multiple people at a company to manage submissions in the FDA Industry Systems. You may already have, or 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 if an employee leaves the facility. For more information on account management, please visit review the FDA Industry Systems User Guide: Account Management.

Figure 2: Establishing Access to the ELM for New Accounts

🛫 U.S. Department of Health and Human Services	Logout
ONLINE ACCOUNT ADMINISTRATION (OAA)	
Create New Account	0 🖨
Create New Account	
You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.	
Step 1: Select Application(s) for Account Creation	
Do you conduct work for a State Agency under Contract with the FDA? If you are creating an account on behalf of a manufacturer, please select "No." O Yes ® No	
Registration and Listing Programs	
Food	
Acidified/Low-Acid Canned Foods Registration	
Acidified/Low-Acid Canned Foods Registration and Process Filing Food Facility Registration Shell Egg Producer Registration	
Acidified!Low-Acid Canned Foods Registration and Process Filing Food Facility Registration Qualified Facility Attestation	
Acidified!Low-Acid Canned Foods Registration and Process Filing Food Facility Registration Qualified Facility Attestation Medical Devices	
△ Acidified!Low-Acid Canned Foods Registration ☑ Export Listing Module and Process Filing □ Shell Egg Producer Registration □ Food Facility Registration □ Shell Egg Producer Registration □ Qualified Facility Attestation ■ Medical Devices ■ □ Device Registration and Listing Module ■	
Acidified!Low-Acid Canned Foods Registration and Process Filing Food Facility Registration Qualified Facility Attestation Medical Devices	

If you are creating a new account, click the box next to "Export Listing Module" to establish access to the ELM. If you need detailed instructions for creating a new account, please visit <u>Create New Account Step-by-Step Instructions</u>.

Figure 3: Launching the ELM from FIS

U.S. Department of Health and Hu	nan Services E ACCOUNT TRATION (OAA)	Logout
Account Management		0 🖶
Account Management		
Change My Password Update System Access	Welcome to the FDA Industry Systems. You are logged You may choose an option on the left to manage your a	ccount or select an FDA system below.
Secret Question/Answer	To obtain access to available FDA systems, choose the Registration and Listing Programs	Update System Access option to add the FDA system to your account.
	Food Food Facility Registration	Export Listing Module
	Acidfied/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation
	Shell Egg Producer Registration	
	Export Certification and Tracking	
	Biologics Export Certification Application and Tracking System	CDER Export Certification Application and Tracking System (CDEReCATS)
	CDRH Export Certification Application and Tracking System (CECATS)	GFSAN Export Certification Application and Tracking System (CFSAN eCATS)
	CVM Export Certification Application and Tracking System (CVM eCATS)	
	FSMA Program(s)	

Once you log in to FDA Industry Systems, you can launch the ELM by clicking "Export Listing Module" in the Registration and Listing Programs section. If the name of the system does not appear in *green* with a checkmark in the box next to it, choose the "Update System Access" option on the left to request access to the ELM.

Figure 4: ELM Dashboard (for first-time users)

and the syste column. Click	em will save these settings. If the "Action Icons" button for	cations associated with your use you can't find one of your applic more information.				r applications. You can per	form all your ac	tions from the Action
Action Ico	ns 🕜					+ Enter New A	pplication	Clear User Settings
Actio	Application Type	Application Number	Product Type	Application Status	Approval Number	Name for Listing	Address	FEI Numbe
	V V							Column
								•
							in Back	Page 0 of 0 1

The ELM dashboard will display all ELM applications associated with your FIS account. First-time users won't have any ELM applications associated with their account, so the dashboard will be empty. To start a new application for an export list, click the "+ Enter New Application" button on the right side of the screen. At any time, you can click on the *question mark* icon in the top right corner of the screen to access step-by-step instructions for using the ELM.

Navigating the ELM Dashboard

Figure 5: Actions on the ELM Dashboard

	the "Action Icons" button for	rou can't find one of your applic more information.	ations, click the "Clear U	ser Settings" button to reset th	e view and display all of you	+ Enter New Appl	-	s from the Action
Actio	Application Type	Application Number	Product Type	Application Status	Approval Number	Name for Listing	Address	FEI Numbe
	V	□ ✓						G.
•/ ×	Renewal Needed	2016000116	Dairy	Approved	2016000116	Test Food Facility Alte	987 Main Str	301478977 3
۲	New	2020000957	Shellfish	Pending Review		Alternate Trade Name	1 Street Addr	301478974
• * ×	Biennial Update	2018000668	Gelatin	Return for Action	2018000668	Food For Export Facility	062020 Main	300821974
• / ×	New	2019000816	Gelatin	Return for Action	2019000816	Test Food Facility DBA	987 Main Str	301478977
۲	Biennial Update	2018000648	Infant Formula	Pending Review	2018000648	Facility Name	1 Street Addr	301478974
4								,

By default, the ELM dashboard will display all the ELM applications associated with your FIS account. You can sort, filter, and rearrange the columns in the table below and the system will save these settings. If you can't find one of your applications, click the "Clear User Settings" button to reset the view and display all your applications. You can use the icons in the Action column to view, edit, or delete each application. Click the "Action Icons" button for an explanation of each icon.

- Select the *eye* icon in the action column to view an application.
- Select the *pencil* icon to edit or renew an application. Please note that you must click through all the screens and resubmit your application to send your edits to FDA.
- Select the red *X* icon to request to delete an application. Please note that if you request to delete an application with an Application Status of "Approved", it will be removed from the export list.

Dashboard Column Controls

Application Type	=	
	∇	

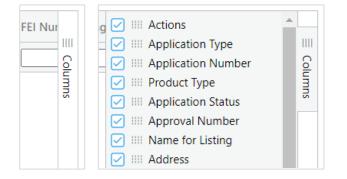
🖈 Pin Column	> !
Autosize This Column	
Autosize All Columns	
Reset Columns	

Each column in the table has tools that can help you navigate your ELM applications. Hover your mouse over the column headers until you see the *hamburger* (three dashes), then click on the hamburger icon to open the column options.

Pin Column moves the selected column to its immediate left or right. **Autosize This Column** expands the selected column to display the character values within the column.

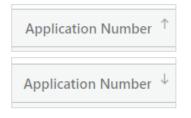
Autosize All Columns expands all columns to display all character values within the columns.

Reset Columns resets the column display to its original (default) state.



is The Columns tab on the right side of the table opens a side panel of all available columns and allows you to select which columns are displayed in the table. Checked columns will be displayed in the table. To hide the side panel, click the Columns tab again.

Sorting, Filtering, Searching



Information for any column can be sorted in ascending or descending order. Click anywhere in the column header to sort by descending order (represented by an arrow pointing down). Click the column header again to sort in ascending order (arrow pointing up). Click a third time to clear the sorting.

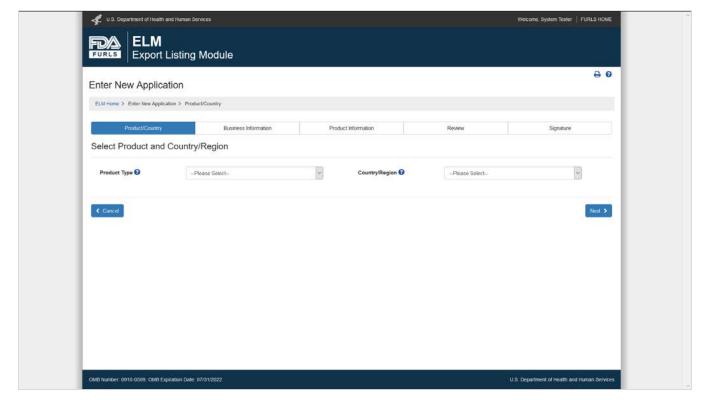
Application Number $\bigtriangledown ~\downarrow$	
2019	\bigtriangledown

To filter for specific information within a column, type into the field below the column header (see left) or click the filter icon to select options from a dropdown menu (see right).

Application Type	Application Number $~^{\downarrow}$
	7
New	Şearch
Biennial Update	🗹 (Select All)
Biennial Update	🗹 Biennial Update
Renewal Needed	New
	Renewal Needed

Submitting or Editing an Application

Figure 6: Product and Country/Region



When submitting a new application, the first screen will prompt you 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.

When editing an existing application, you will not see this screen and cannot edit this information. If you need to apply for a different export list, return to the ELM home page and submit a new application.

Figure 6.1: Product and Country/Region for Shellfish Applications

U.S. Department of Health and He	uman Services			FURLS HOME
FURLS ELM	ting Module			
≡Menu	-			0
Enter New Applicatio	11			
ELM Home > Enter New Application	> Product/Country			
Product/Country	Business Information	Product Information	Review	Signature
Select Product and Co	untry/Region			
Product Type 🕜	OballEab	✓ Country/Region €	Furances Unice (FU)	~
	Shellfish	County/Region	European Union (EU)	•
< Cancel				Next >
OMB Number: 0910-0509, OMB Expiration	n Date: 07/31/2022			U.S. Department of Health and Human Services

If you select **Shellfish** as the Product Type and the **European Union (EU)** as the Region, the facility must appear on the <u>Interstate Certified Shellfish Shippers List</u> (ICSSL). After making your selection, click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 7: Identifying the Facility for Listing

U.S. Department of Health and Human				Welcome, System Tester FURLS HOME
FURLS ELM Export Listin	a Module			
				0
Enter New Application				
ELM Home > Enter New Application > Bu	siness Information			
Product/Country	Business Information	Product Information	Review	Signature
Facility Information				
Facility Information				
Please select one of the following option	ns to identify the facility for inclusion on the exp	port list.		
Food Facility Registration				
FEI Number				
O DUNS Number				
Previous				Next >

For most applications, you may identify the facility for listing by selecting a Food Facility Registration (FFR) associated with your FIS account, entering an FDA Establishment Identifier (FEI Number), or entering a DUNS number.

Please note: The ELM will auto-populate your name and address for listing from FDA records based on the way that you identify the facility. Most firms prefer 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. If you do not see a Food Facility Registration option, that means there are no registrations associated with your FIS account. For more information, please see <u>Appendix A: Using the Food Facility Registration in ELM</u>.

- If you use an FFR to identify the facility on the application, the ELM will pull in the "Facility Address" from section 2 of the FFR. The facility address in the FFR is supposed to be the physical location of the facility. You will be able to select any name associated with the FFR as the name for listing the facility on the export list.
- If you use the FEI or DUNS to identify the facility on the ELM application, the ELM will pull the
 "Physical Address" associated with the facility's record in FDA's Official Establishment Inventory.
 This may or may not match the facility address in the FFR. (Seafood vessels will also have the
 option of selecting the "Mailing Address" associated with the facility's record in FDA's Official
 Establishment Inventory.) The ELM will pull the legal name of the facility from Official Establishment
 Inventory, but you will have the option of specifying another name for listing.

For shellfish facilities that are included on the Interstate Certified Shellfish Shippers List (ICSSL), please see <u>Figure 7.1 State and Certificate Information</u>.

Figure 7.1: ICSSL State and Certificate Information for Shellfish Facilities

🖑 U.S. Depar	tment of Health and Huma	In Services						FURLS HOME
	ELM Export Listi	ng Module						
^{≡ Menu} Enter Nev	v Application							0
	inter New Application > I	Business Information						
Pro	duct/Country	Business Information		Product Information		Review	Signature	
State and	Certificate Info	ormation						
		ellfish shipper is located and the certificate num scripts/shellfish/sh/shellfish.cfm.	ber as ide	ntified on the Interstate Certified S	hellfish Shippers	s List:		
State		Please Select	~	Certificate Numbe	r)
Previous								Next >
OMB Number: 0910	0-0509, OMB Expiration D	ate: 07/31/2022					U.S. Department of Health and H	luman Services

Facilities applying for inclusion on the EU shellfish list must be included on the Interstate Certified Shellfish Shippers List (ICSSL) and will be prompted to identify the state where the facility is located and the certificate number from the ICSSL.

You may visit <u>https://www.cfsanappsexternal.fda.gov/scripts/shellfish/sh/shellfish.cfm</u> to search for your certificate number. Note: If your ICSSL certificate number contains one or more leading zeroes (e.g., a zero as the first digit), you must enter those zeroes to find the record for your facility.

Figure 7.2: Identifying the Facility for Listing for Shellfish Firms

U.S. Department of Health and Human Ser	rvices			FURLS HOME
FURLS Export Listing	Module			
≡ Menu				0
Enter New Application				
ELM Home > Enter New Application > Busin	ess Information			
Product/Country	Business Information	Product Information	Review	Signature
Facility Information				
Facility Information				
Please select one of the following options t option to identify the facility on the ELM ap Food Facility Registration		ility that should be included on the export list	t. If this facility is also included on other expo	nt lists, you should choose the same
O FEI Number				
O DUNS Number				
O Interstate Certified Shellfish Shippers L	.ist (ICSSL)			
1 Devicions				
< Previous				Next >

OMB Number: 0910-0509, OMB Expiration Date: 07/31/2022

U.S. Department of Health and Human Services

You may identify a shellfish facility for listing by selecting a Food Facility Registration (FFR) associated with your FIS account, entering an FDA Establishment Identifier (FEI Number), entering a DUNS number, or using the previously-provided ICSSL information.

Please note: The ELM will auto-populate your name and address for listing from FDA records based on the way that you identify the facility. See <u>Figure 7: Identifying the Facility for Listing</u> for more information on the FFR, FEI, and DUNS options. If this facility is also included on other exports lists, you should choose the same option to identify the facility on the ELM applications for all export lists.

Figure 7.3: Identifying the Facility with the Food Facility Registration

Linter Her	Application				
ELM Home > E	ter New Application > Business Info	mation			
Pro	duct/Country	Business Information Produc	tinformation	Review	Signature
Facility	2 of 2 entries	of see the facility for which you would like to apply, you ma	Preturn to the previous screen and se	sect another option for identifying	Filer.
-	Test Food Facility		967 Main Street, Washington, DC	C, 20011, US	
0	Facility Name		1 Street Address, 2 Street Addres	ss, Seattle, WA, 98121, US	
0					

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 FDA Industry Systems 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 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, exit the ELM and click on the "Food Facility Registration" link from the 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. For help with the Food Facility Registration system, please visit <u>Online Registration of Food Facilities</u>.

Once you have successfully linked your Food Facility Registration to your FIS account, you can return to the ELM and use the Food Facility Registration to identify the facility.

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FIGURE /	4. IOENTIT	vina the F	-acility with	The FFI	Number
inguic i		ynng thte i	active when		1 turno ci

Enter New Application	Business Information			
Product/Country	Business Information	Product Information	Review	Signature
Facility Information				
Facility Information				
 Food Facility Registration FEI Number 				
DUNS Number				
O DUNS Number				
O DUNS Number				

If you choose to identify the facility for listing 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 receive an error message, please contact <u>CFSANExportCertification@fda.hhs.gov</u> for assistance.

If you do not know the FEI number for your facility, you can contact

<u>CFSANExportCertification@fda.hhs.gov</u> or visit the FDA <u>FEI Portal</u>. The FEI Portal allows a user to look up an FEI number based on a firm name and address.

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FIGURE	ר /	IDENTITY	νιηα τη	е ғасші	v with	The		Number
ingale		i a ci i ci i	,	e i aciii	.,		0.10	1 tanno ci

Enter New Application				⊖ 0
ELM Home > Enter New Application > Bu	usiness Information			
Product/Country	Business Information	Product Information	Review	Signature
Facility Information				
Facility Information				
Please select one of the following options	s to identify the facility for inclusion on the export	tis		
Food Facility Registration				
O FEI Number				
FEI Number DUNS Number				
O FEI Number				
FEI Number DUNS Number				
FEI Number DUNS Number DUNS Number				
FEI Number DUNS Number				

If you choose to identify the facility for listing by the DUNS number, enter the DUNS number and click Next.

You may visit <u>https://fdadunslookup.com/</u> to search for or request a valid DUNS number. Note: DUNS numbers contain 9 digits. If your DUNS number contains a leading zero (i.e., a zero as the first digit), you must enter that zero to find the record(s) for your facility.

If there are multiple facilities associated with the DUNS number, you will have the option to select the correct name and address. If there are multiple records with the same or similar names/addresses, you may contact <u>CFSANExportCertification@fda.hhs.gov</u> for assistance in choosing the correct record. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 7.6: Identifying the Facility with the Interstate Certified Shellfish Shippers List (ICSSL)

U.S. Department of Health and Human	1 Services			FURLS HOME
FURLS ELM	ng Module			
≡ Menu				₽ 0
Enter New Application				
ELM Home > Enter New Application > Bu	usiness Information			
Product/Country	Business Information	Product Information	Review	Signature
Facility Information				
Facility Information				
Please select one of the following option option to identify the facility on the ELM	ns to identify the name and address of the faci I applications for all export lists.	ility that should be included on the export list	t. If this facility is also included on other expo	ort lists, you should choose the same
O Food Facility Registration				
O FEI Number				
O DUNS Number				
Interstate Certified Shellfish Shippe	rs List (ICSSL)			
< Previous				Next >
OMB Number: 0910-0509, OMB Expiration Dat	te: 07/31/2022			U.S. Department of Health and Human Services

If you choose to identify the facility for listing by the Interstate Certified Shellfish Shippers List (ICSSL) number, select the ICSSL option and click Next.

This option is for shellfish facilities only and will use the information provided in the State and Certificate Information section to populate the name and address for listing from the name and address on the ICSSL; please see Figure 7.1 State and Certificate Information.

Figure 8: Existing Application Error

Entor How	Application				
ELM Home > En	er New Application > Business Information				
Proc	luct/Country Bus	siness Information Produc	:t Information	Review	Signature
		Product Product	s monification	PLEVELY	Signature
Facility Info	manon				
ERROR: The fa	cility from the list below. If you do not see the cility you selected is the subject of exist	nd selecting "Link Registration to your Account" fro he facility for which you would like to apply, you ma sting application 202000957 for this export list se contact CFSANExportCertification@fda.hhs	y return to the previous screen	and select another option for identifying t home page and edit the existing appl	1
ERROR: The fa	city from the list below if you do not see th sillity you selected is the subject of exis product type, or facility identifier. Please	the facility for which you would like to apply, you ma sting application 2020000957 for this export list	y return to the previous screen	and select another option for identifying t home page and edit the existing appl	1
ERROR: The facountry/region	city from the list below if you do not see th sillity you selected is the subject of exis product type, or facility identifier. Please	the facility for which you would like to apply, you ma sting application 2020000957 for this export list	y return to the previous screen	and select another option for identifying t home page and edit the existing appl	1
ERROR: The facountry/region	city from the list below If you do not see th city you selected is the subject of exis ,enduct type, or facility identifier. Pleas 2 of 2 entries	he facility for which you would like to apply, you ma sting application 2020000857 for this export list se contact CPSANE-portCenification@fda.hhs	y return to the previous screen	and select another option for identifying t home page and edit the existing appl	ication or select a different
ERROR: The fa country/region Facility Showing 1 to Show 10	citly from the list below If you do not see th citly you selected is the subject of exis ,eroduct.type, or facility identifier, Please 2 of 2 entines entities	he facility for which you would like to apply, you ma sting application 2020000857 for this export list se contact CPSANE-portCenification@fda.hhs	y return to the previous screen . You may return to the ELM . gov if you have any questio	and select another option for identifying appl home page and edit the existing appl	ication or select a different
ERROR: The fa country/region Facility Showing 1 to Show 10 Select	citly from the less below If you do not see If elity you selected is the subject of exis product type, or facility identifier. Please 2 of 2 entires entires Facility Name	he facility for which you would like to apply, you ma sting application 2020000857 for this export list se contact CPSANE-portCenification@fda.hhs	y return to the previous screen . You may return to the ELM	and select another option for identifying appl home page and edit the existing appl	ication or select a different

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.

If you receive an error message that directs you to the ELM home page, return to the ELM home page and look for the existing application that is associated with your FIS account.

If the existing application is not associated with your FIS account, please contact <u>CFSANExportCertification@fda.hhs.gov</u> for assistance and provide the existing application number.

Figure 9: Parent Company Name/Address Information

				0 6
Enter New Applicat	ion			
ELM Home > Enter New Applicat	on > Business Information			
			Review	Signature
Product/Country	Business Information	Product Information	Revew	Signature
Product/Country Business Information		Product Information	Review	Synaure
Business Information				
Business Information Some information below is pre-pop	1			
Business Information Some information below is pre-pop	ا ulated from your Food Facility Registration (FFR). If you war			
Business Information Some information below is pre-pop Parent Company Name/Ac	ulated from your Food Facility Registration (FFR). If you war idress Information (Optional)	nt to edit any information in the Facility information	or Listing section, you must first update th	
Business Information Some information below is pre-pop Parent Company Name/Ac Company Name	ulated from your Food Facility Registration (FFR). If you war idress Information (Optional)	nt to edit any information in the Facility information	or Listing section, you must first update th	
Business Information Some information below is pre-pop Parent Company Name/Ac Company Name	ulated from your Food Facility Registration (FFR). If you war idress Information (Optional)	nt to edit any information in the Facility Information Country/Region Address Line 1	Or Listing section, you must first update th UNITED STATES 1 PC Address	

After identifying 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 used an FEI number, a DUNS number, or ICSSL information, this section is not prepopulated and you may enter this information. The *Doing Business As* field is optional regardless of how you identify the facility.

Figure 10: Main Contact Information

Main Contact Informat	01					
First Name	System	Telephone	001	555	5555555	Te .
			Country	Area	Phone Number	Ext
Last Name	Tester	Fax (Optional)	001		731	
			Country	Area	Fax Number	
Email	FDAIndustrySystemsTester@gmail.com					

The Main Contact Information is prepopulated from your FDA Industry Systems account. You may edit this information if needed. Notifications about this application will be sent to this email address.

For more information about managing your FIS account, please visit <u>FDA Industry Systems Account</u> <u>Management Guide</u>.

Facility Information for Listing

Figure 11: Facilities Identified by FFR

The full sector from the sector				
The following Pacility Name and	d Address will be used for the Country List.			
Facility Type	Processing Plant	Y	Facility Address Line 1	1 Street Address
Name for Listing	-Please Select-	0	Facility Address Line 2 (Optional)	2 Street Address
			Zip/Postal Code	98121
			City	Seattle
			State/Territory	Washington

Facility Type

If the "Facility Type" is not prepopulated on your application, you must select a "Facility Type" from the dropdown menu. The options will vary based on the product type and country/region associated with your application. The "Facility Type" selection affects how the facility is listed on the export lists, so please see <u>Appendix B</u> for a list of "Facility Type" options and the associated designations for export lists.

Name and Address for Listing

If your application is approved, the "Name for Listing" and the address in this section will be included on the export list. Please confirm that these fields are accurate before proceeding with the application.

Name for Listing

If you identified the facility using a Food Facility Registration (FFR), you will have the option of selecting any name associated with your FFR as the "Name for Listing". If you do not see the name with which you wish to be listed, you may update your FFR to edit an existing name in the FFR or provide an "Alternate Trade Name". If you need to edit your FFR, save the ELM application as a draft and exit the application, then update your FFR and return to the ELM to finish your draft application.

Address for Listing

If you identified the facility using a Food Facility Registration (FFR), the address for listing will be prepopulated with the facility address from section 2 of the FFR. If the address that appears in the ELM is incorrect, you should update the facility address in section 2 of the FFR before continuing with your ELM application. To edit your FFR, save the ELM application as a draft and exit the application, then update the FFR and return to the ELM to finish the draft application.

Facility Information for List	ing			
The following Facility Name an	nd Address will be used for the Country List.			
Facility Type	Piease Select	✓ Facility Address Line 1	1 Street Address	
Firm Name	Facility Name	Facility Address Line 2 (Optional)	2 Street Address	
Name for Listing	Facility Name	Zip/Postal Code	20011	
		City	Washington	~
		State/Territory	District of Columbia	~

Figure 12: Facilities Identified by FEI or DUNS Number

Facility Type

If the "Facility Type" is not prepopulated on your application, you must select a "Facility Type" from the dropdown menu. The options will vary based on the product type and country/region associated with your application. The "Facility Type" selection affects how the facility is listed on the export lists, so please see <u>Appendix A</u> for a list of "Facility Type" options and the associated designations for export lists.

Name and Address for Listing

If your application is approved, the "Name for Listing" and the address in this section will be included on the export list. Please confirm that these fields are accurate before proceeding with the application.

Name for Listing

If you identified the facility using a FEI or a DUNS number, the "Firm Name" and "Name for Listing" field will be prepopulated with the legal firm name that FDA has on record for your facility. You may edit the "Name for Listing" field if you wish to be listed by another name.

Address for Listing

If you identified the facility using a FEI or a DUNS number, the address for listing will be prepopulated with the physical address associated with the facility's record in FDA's Official Establishment Inventory. If the physical address that appears in the ELM is incorrect, please save the application as a draft and contact <u>CFSANExportCertification@fda.hhs.gov</u> to request an update to the facility's record in FDA's Official Establishment Inventory. You can continue with your ELM application once the facility's record has been updated to reflect the correct physical address.

Figure 12.1: Address Options for Seafood Vessels

Facility Information for List	ing			
The following Facility Name an	nd Address will be used for the Country List.			
Facility Type	Factory Vessel	V Facility Address Line 1	1 Street Address	
Firm Name	Facility Name	Facility Address Line 2 (Optional)	2 Street Address	
Name for Listing	Facility Name	Zip/Postal Code	20011	
Vessels may choose to be Choose Facility Address	isted with their physical address or their mailing address.	City	Washington	*
SUSSESSESSES SUSSESSES		State/Territory	District of Columbia	~

If you identified the facility using a FEI or a DUNS number and you select **Freezing Vessel or Factory Vessel** as the "Facility Type", you may choose to be listed with either the physical address or the mailing address associated with the facility's records in FDA's Official Establishment Inventory. Click on the "Choose Facility Address for Listing" option to select an address for listing.

The following Facility Name and Address will be used for the Country List.		
Address Selection		×
Physical Address	Mailing Address	
1 Street Address, 2 Street Address, Washington, DC - 20011	1 Street Address, 2 Street Address, Washington, DC - 20011	
USE THIS ADDRESS	USE THIS ADDRESS	

If either the physical address or the mailing address that appears in the ELM is incorrect, please save the application as a draft and contact <u>CFSANExportCertification@fda.hhs.gov</u> to request an update to the facility's record in FDA's Official Establishment Inventory. You can continue with your ELM application once the facility's record has been updated to reflect the correct address.

Please note that there is no option to select a mailing address if you use the FFR to identify the facility. If you wish to list a vessel with a mailing address, you must use the FEI to identify the facility.

Figure 13: Facilities Identified by ICSSL Certificate Number

Facility Information for Listing		
The following Facility Name and Address will be used for the Country List. Facility Type	Facility Street Address Line 1	
Does this facility also export processed shellfish products?	Facility Street Address Line 2 (Optional)	
Name for Listing	Zip/Postal Code	
	City	\sim
	State/Territory	

Facility Type

For ICSSL facilities, the facility type is automatically populated based on the ICSSL activities for which the facility is certified. You must indicate whether the facility also exports processed shellfish products. The "Facility Type" selection affects how the facility is listed on the export lists. See <u>Appendix A</u> for a list of "Facility Type" options and the associated designations for export lists.

Name and Address for Listing

The name and address for listing fields are automatically populated from the ICSSL.

Figure 14: Inspection Details

Inspection Details (Optional)		
If the facility has not had a recent inspection by FDA, you may provide information about	It the facility's most recent inspection below.	
Plant Identifier	Last Inspection Date (MM/DD/YYYY)	
		
Government Agency That Provided Inspection	Copy of Last Inspection Notice	
Please Select	Browse No file selected	A Upload
	Allowed file types are jpg. jpeg. doc. docx. txt. xls. xlsx. pdf. gif.	and of The maximum file size is 60 MR

The Inspection Details section is optional. If your facility has been inspected by FDA, you do not need to complete this section. If your facility has not been inspected by FDA, providing the details for your most recent inspection will prevent delays in the application review process. The inspection report must clearly identify the name and address of the facility for which you are applying, the inspecting agency, the purpose of the inspection, and the inspection result.

Select the "Browse" button to find the document you wish to upload. 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. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 15: Additional Documents

U.S. Department of Health and Human	1 Services			Welcome, System Tester FURLS HOME
FURES ELM Export Listin	g Module			
Enter New Application				80
ELM Home > Enter New Application > Bo	usiness Information			
Product/Country	Business Information	Product Information	Review	Signature
Additional Documents				
Upload Additional Documentation	(as applicable):			
Browsc No file selected.				A Upload
Allowed file types for the addition	nal documents are .jpg, .jpeg, .doc, .docx, .bxt, .3	kis, .xlsx, .pdf, .gif, and .rtf. The maximum file size is	50 MB.	
< Previous				Save And Exit > Next >

Use the *Additional Documents* section to upload any additional documents that are required for review of your application. Select the "Browse" button to find the document you wish to upload. 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 most applications, no additional documents are required. Some circumstances in which you may need to upload additional documentation include:

- If you wish to be listed with an approval number that differs from FDA's general policy for approval numbers, you may upload a letter that includes the firm's name, address, current approval number (if applicable), and the desired approval number. For more information about approval numbers, visit <u>Online Applications for Export Lists</u>.
- For the China seafood export list, upload an audit letter or other evidence of third-party certification in this section. For more information, visit <u>Seafood Exports to the European Union and China</u>.
- For the European Union (EU) Collagen and Gelatin export lists, upload laboratory results in this section. For more information, visit <u>Collagen and Gelatin Exports to the European Union</u>.

Figure 16: Additional Contact Information

Enter New Application ELM Home > Enter New Application > Pr	oduct information						
Product/Country	Business Information	Product Info	ormation	Review			Signature
Country European Union	(EU)		Product Type	Shelfish			
						O A	tofil Man Contact Informa
Contact Information							
First Name			Telephone	001 Country	Area	Phone Number	Ext
Last Name			Fax (Optional)	001	Area	Fax	
Title			Email	Country	Area	Fax Number	
			- manual distance of the second se				

You may identify an additional contact to receive updates about this application. To ensure that your company receives system notifications and that FDA can contact your firm if needed, we strongly recommend that you identify a second contact to receive notifications about this application in addition to the main contact identified on the first page of the application. You may wish to use a general phone number and email address to ensure that FDA can reach somebody at your facility about this application. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Product Information

The fields on the product information screens will vary depending on the product type and country/region selected.

oduct Information			
Country European Union (EU)		Product Type	Dairy
Animal Origin	Please Select	•	
Product			
Schedule B/HTS Number 😯			
Value of Goods (Optional) 😯			
Quantity (Optional) 😧			
Unit of Measure 😯	Please Select	•	
Is this product shipping within the next two years?	Please Select	•	
Previous			>

Figure 17: EU Dairy Product Information

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure	18:	China	Dairy	Product	Informatio	n

Animal Origin	Please Select		
	Bovinae Bovine		
Product Category	Caprine Ovine		
Product Name (Optional)	Ovine		
Schedule B/HTS Number 💡	[
Value of Goods (Optional)	[
Quantity (Optional)			
Unit of Measure 😮	-Please Select-	~	
Is this product currently being manufactured and ready to ship?	Please Select V		

Enter all required information. Select from the product category dropdown the option that best describes your product. If you have question regarding the product category please reference the <u>AQSIQ</u> <u>Implementation Catalogue</u>. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure	19:	Chile	Dairy	Product	Information

Product Information			
Country Chile		Product Type	Dairy
Animal Origin	Please Select	-	
Product			
Schedule B/HTS Number 😯			
Value of Goods (Optional) 😧			
Quantity (Optional) 🚱			
Unit of Measure 🚱	Please Select	▼.	
Is this product shipping within the next two years?	Please Select	•	
< Previous			> Nex

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 20: China Seafood Product Information

Product Information		
Country China	Product Type	Seafood
Product		
Schedule B/HTS Number 🚱		
Value of Goods (Optional) 😧		
Quantity (Optional) 😧		
Unit of Measure 😧	Please Select	·
Aquaculture Product	Please Select	
Bivalve Mollusk	Please Select	
Is this product currently being manufactured and ready to ship?	Please Select	
< Previous		> Next

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Note: If you indicate that one of your products is an aquaculture product, this will be indicated on the China list with an "A" in the Remarks column. If you indicate that one of your products is a bivalve mollusk product, this will be indicated on the China list with a "BMS" in the Remarks column.

Figure 21: EU Seafood Product Information

Enter New Application	ormation				
Product/Country	Business Information	Product Information		Review	Signature
Product Information					
Country European Union (EU)		Product 1	ype	Seafood	
Product					
Schedule B/HTS Number 🕜					
Value of Goods (Optional)					
Quantity (Optional)					
Unit of Measure 🕜		Select-	۷		
Aquaculture Product		Select-			
is this product snipping within the nex	t two years?Picase	Select V			

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Note: If you intend to export aquaculture products, you must indicate that on your application so that your EU listing contains an "Aq" in the Remarks column.

Figure 22: EU Shellfish Product Information

Enter New Application ELM Home > Enter New Application > Product Information				
Product/Country Business In	ormation Product Info	rmation	Review	Signature
Product Information				
Country European Union (EU)		Product Type	Shellfish	
Product				
Schedule B/HTS Number 😧				
Value of Goods (Optional) 🕢				
Quantity (Optional) 🕑				
Unit of Measure 🕜	Please Select			
Aquaculture Product	Please Select	*		
Is this product shipping within the next two years?	-Please Select-	2		

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Country China	Product Type	Infant Formula	
Animal Origin	Please Select	~	
Product	Please Select Bovine		
Schedule B/HTS Number 😯			
Infant Formula Number (Optional)			
Infant Formula Type	Please Select	~	
Value of Goods (Optional) 😯			
Quantity (Optional) 🕢			
Unit of Measure 😮	Please Select	~	
Is this product currently being manufactured and ready to ship?	Please Select V		
Unit of Measure 😯 Is this product currently being manufactured			

Figure 23: Infant Formula China Product Information

Enter all required information. The Infant Formula Number (IFN) is required for review of the export list application. Please reference the <u>AQSIQ Implementation Catalogue</u> for questions regarding the Infant Formula Type. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 24: EU Collagen Product Information

Country European Union (EU)		Product Type	Collagen	
Animal Origin	Please Select	~		
Product		1		
Schedule B/HTS Number 🕜				
Value of Goods (Optional) 😯				
Quantity (Optional) 🕜				
Unit of Measure 😮	Please Select	~		
Is this product shipping within the next two years?	Please Select	~		

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Note: If you indicate that the animal origin of the product is "Fish", you must indicate whether the product was derived from aquaculture products. If you intend to export collagen derived from aquaculture products, you must indicate that on your application so that your EU listing contains an "Aq" in the Remarks column.

Animal Origin	Please Select Bovinae		
Product	Bovine Caprine Ovine		
Schedule B/HTS Number 😧	Fish Poultry Suidae		
Value of Goods (Optional) 😧			
Quantity (Optional)			
Unit of Measure 😮	Please Select	~	
Is this product shipping within the next two years?	Please Select V		

Figure 25: EU Gelatin Product Information

Enter all required information. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Note: If you indicate that the animal origin of the product is "Fish", you must indicate whether the product was derived from aquaculture products. If you intend to export collagen derived from aquaculture products, you must indicate that on your application so that your EU listing contains an "Aq" in the Remarks column.

Figure 26: Product List

	cation									⊖ 6
ELM Home > Enter New Ap		ation								
Product/Count	ÿ	Business Informat	on Pro	duct Inf	ormation			Review		Signature
Product List										
To edit a product, click the To delete a product, click the <u>CONFIRMATION: Produ</u> Facility Details	icon next to the product	information below	Country					Product Type		
Alternate Trade Name #4 1 Street Address, Seattle,	NA 98121		European Union (EU)					Shelfish		+ Add Product
Showing 1 to 1 of 1 entries Show 5 v entries										Fitter
Action Product		Aquaculture Product Il	Schedule B/HTS Number	11	Value of Goods	IT .	Quantity	Unit of Measure	11	Shipping within the next two years?

When you add a product to the application, you'll see a *Product List* page with all the products associated with the application.

To add additional products to your application, click the "+ Add Product" button. To edit information for a product, click on the *pencil* icon. To remove a product from the application, click on the *X* icon.

Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 27: Application Review

FURLS Export Lis	sting Module			
Enter New Application	on			⊖ 0
ELM Home > Enter New Application	> Review			
Product/Country	Business Information	Product Information	Review	Signature
Please review the information entered	d for the Shellfish Facility. Please select the "Edit" button	s next to each section to update. Click "Next" to submit the	application.	
Country/Region				🖉 Edi
Country	European Union (EU)	Product Type	Shelfish	
Please identify the type of facil	lity for inclusion on the export list Shellfish process	sor that does not appear on the Interstate Certified Shellfish	Shippers List (ICSSL)	
Facility Information				🖉 Eat
Facility Information	Food Facility Registration	FFR Number	19679214294	
Business Information				🖉 Eat
Parent Company Name/Addre	ess Information			
Company Name Address Line 1 City Zip/Postal Code	Parent Company Name 1 PC Address Seattle 96121	Doing Business As (Option Address Line 2 (Optional) State/Province/Territory Country/Region	al) 2 PC Address Washington UNITED STATES	
Main Contact Information				
First Name	System Tester	Telephone Fax (Optional)	001-565-555555	
Last Name Email	FDAIndustrySystemsTester@gmail.com			

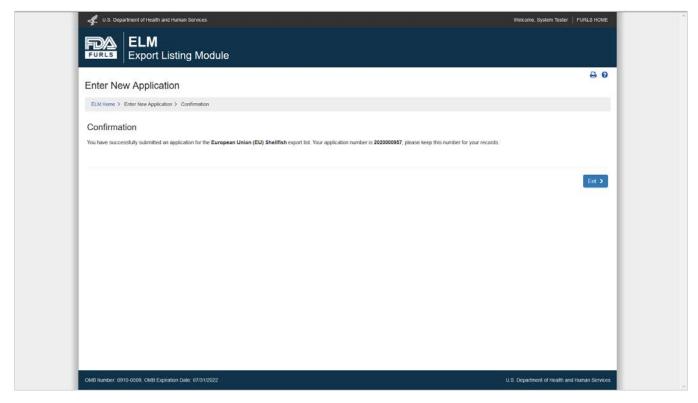
Please review all the information you provided on your application on the *Application Review* page. If you need to correct or update any information, click the "Edit" button in the relevant section of the application. Click the blue "Next" button at the bottom of the screen to proceed with the application.

Figure 28: Signature Page

	ELM Export Listing	g Module			
Edit Appli	cation				0 0
ELM Home > E	dit Application > Signature				
Pn	oduct/Country	Business Information	Product Information	Review	Signature
Signature	Page				
2. The produ 3. The produ 4. The produ The undersigned	acts listed on this application acts listed on this application acts listed on this application certifies that the information re information on this list, wh	are not the subject of a pending judicial enforc are being exported from the United States. In this submission is complete and accurate. T	uired by the FD&C Act. If States or meet the requirements of Section 80 ement action (e.g., an injunction or seizure) or a he undersigned understands that the information g that it will be communicated to the competent.	pending administrative action (e.g., warning le	lishing and maintaining a list of exporters
Knowingly and up to 5 years in		g false statements on any documents submitte	d to FDA may constitute violations of the United	States Code Title 18, Section 1001 with penal	ties including up to \$250,000 in fines and
					✓ Submit
< Previous					- Courter

Review the statement on the signature page and if you agree, check the box labeled "I Agree." Click the blue "Submit" button at the bottom of the screen to submit the application to FDA.

Figure 29: Confirmation Page for New Applications



Once you submit your application, you will see a confirmation page and receive an application number. Keep this number for future inquiries about your application.

Figure 30: Confirmation Page for Draft Applications

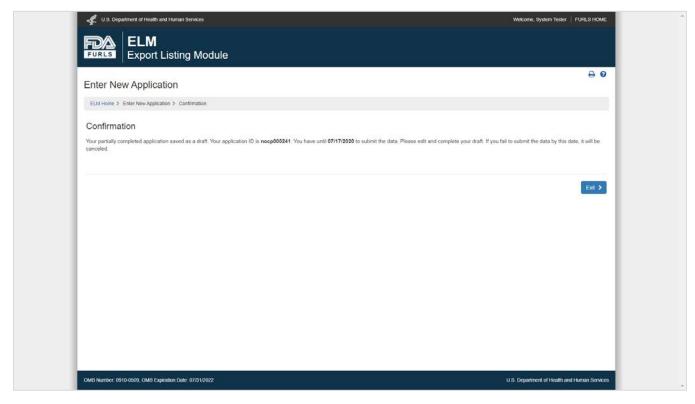
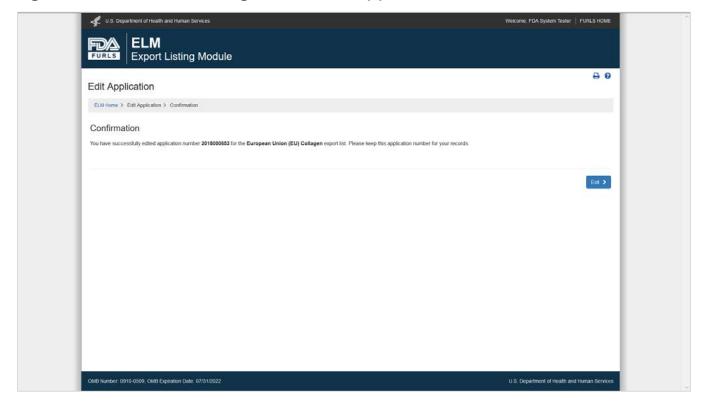


Figure 31: Confirmation Page for Edited Applications



Appendix A: 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.

Appendix B: Email Notifications from the ELM

The ELM sends the following email notifications to the email addresses for the contacts on the application. FDA strongly recommends that applicants identify two different contacts to receive notifications about ELM applications.

Notifications about Submissions

- Draft Application Saved
- Application Received
- Edit/Biennial Update Received

Notifications about Changes in Application Status

- Application Approved
- Application Returned for Action
- Application not Deleted
- Application Rejected or Deleted
- Application Expired

Reminder Notifications

- Draft Application Reminder
- Biennial Update Reminder (6 months prior to expiration)
- Biennial Update Reminder (3 months prior to expiration)
- Biennial Update Reminder (1 month prior to expiration)

Appendix C: Product, Country, and Facility Type Matrix

Product Type	Country	Facility Type Options	Activities Designation for Country Lists
Collagen	European Union (EU)	Processing Plant	PP
Dairy	Chile	Co-packer	N/A
Dairy	Chile	Processing Plant	N/A
Dairy	China	Co-packer	PP
Dairy	China	Processing Plant	РР
Dairy	European Union (EU)	Co-packer	PP
Dairy	European Union (EU)	Processing Plant	PP
Gelatin	European Union (EU)	Processing Plant	РР
Infant Formula	China	Processing Plant	PP
Seafood	China	Cold Stores	CS
Seafood	China	Factory Vessel	FV
Seafood	China	Freezing Vessel	ZV
Seafood	China	Processing Plant	PP
Seafood	European Union (EU)	Broker	PP (with O! in the Remarks column)
Seafood	European Union (EU)	Cold Stores	CS
Seafood	European Union (EU)	Factory Vessel	FV
Seafood	European Union (EU)	Freezing Vessel	ZV
Seafood	European Union (EU)	Processing Plant	РР
Shellfish	European Union (EU)	Depuration Processor*	PC, IP
Shellfish	European Union (EU)	Repacker*	IP
Shellfish	European Union (EU)	Reshipper*	IP
Shellfish	European Union (EU)	Shell Stock Shipper*	IP
Shellfish	European Union (EU)	Shucker-Packer*	IP

* For facilities on the Interstate Certified Shellfish Shippers List (ICSSL), the facility type will automatically populate based on the ICSSL activities for which the facility is certified.