## STEP BY STEP GUIDE TO CREATE YOUR FDA PRIOR NOTICE

Fed X.

Feb 2021

## **Creating a Prior Notice is a 2 steps process.**

	FOOD AND	DRUG ADMINIS STEMS	TRATIO	N	Iome   FIS Home	0.
DA Industry Sy	/stems			30	heck System Status	
IS was created, in part, in upply. The Act requires the tended for consumption is in, facilities must be regist systems Index	response to the Bictern at FDA develop two syst n the United States and tered by December 12.	orium Act of 2002, which gave high p terms: one to support the registration one to receive prior notice before for 2003 when Prior Notice went into effe	riority to improved of facilities that ma id is imported or of ect.	information management to nuflecture, process, pack, or fered for import into the Unit	help protect the food hold food products od States. Under the	0
IS was created, in part, in upply. The Act requires the tended for consumption is in, facilities must be regist <b>Systems Index</b> FURLS Acidified/Low Ar (LACF) Form 2541/2541d/2541e( OMB Approval Number 10/ See OMB Burden Statem	response to the Biotern at FDA develop two syst in the United States and tered by December 12. cld Canned Foods (2541f/2541g 910-0037 31/2023 soft	FURLS Biologics Export Certi Application & Tracking Syster Form 5613 (05/18) OV/8 Approval Number 0910-04 OV/8 Expiration Date 04/30/202 See OMB Burden Statement	riority to improved of facilities that ma d is imported or of ect. iffication m (BECATS) 998 11	FURLS Export Listing I Form 3972 (07/18) OMB Approval Number 0 OMB Suppration Date 07 See OMB Burden State	Module (ELM)	02

Step 1: Create your web entry:

submitter, importer and carrier nformation.



Step 2: **Create the Prior Notice**: detailed product information

#### **Step 1: Create your web entry**

#### Go to: access.fda.gov

Change My Passwo

Update System Acc

Deactivate a Subac

Reactivate a Subac

- Login with your account ID and Password
- Select the "Prior Notice interface" option

d	You may choose an option on the left to manage your account of To obtain access to available FDA systems, choose the <b>Update</b>	or select an FDA system below. • System Access option to add the FDA system to your acc
SS		
	Registration and Listing Programs	
ount	Food	
unt	Food Facility Registration	Export Listing Module
un	Acidified/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 (BECATS)	CDER Export Certification Application and Tracking System (CDER eCATS)
	CDRH Export Certification Application and Tracking System (CECATS)	CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
	CVM Export Certification Application and Tracking System (CVM eCATS)	
	FSMA Program(s)	
	Accredited Third-Party Certification Program Accreditation Body	Voluntary Qualified Importer Program
	Accredited Third-Party Certification Program Certification Body	
	Foreign Supplier Verification Program	
	Other FDA Systems	
	Prior Notice System Interface	Systems Recognition Program
	Import Trade Auxiliary Communication System (ITACS)	CBER Biological Product Deviation Reporting (CBER eBPDR)

- For a new Prior Notice submission, select "Create New Web Entry."
- Note: If you have already started a Web Entry or Prior Notice and want to go back to it, choose either "Find Existing Web Entry" or "Find Existing Prior Notice."

#### **1- Entry Information**

- Entry type. Transportation and Exportation: Consumption, Express Courier
- Entry identifier: if not known, select the **"Not Known"** check box
- The number of prior notices: you will need to create 1 Prior notice (PN) per product type. If your shipment contains the same product but a different packaging you will need to create one PN by packaging type

*i.e.* if you ship 2 bottles of similar type of wine, 1 of 1 liter and 1 of 2 liters you will need to create 2 PN.

### 2- Port of arrival information

#### (if you ship with FedEx)

Port of Arrival				
Enter the Port Code for the Port of Arrival and the Arrival Date and Time. Please note if the Arrival Date and Time is in the past then this Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Anticipated Arrival Date and Time. The time should be in the time zone of the Port of Arrival. If you do not know the Port Code, select the state and click on the Find Port Code button.				
Port	a			
State:	Tennessee V	1		
	OR Port Code: 2095			
Anticipated Arrival Date:	:: 12/21/2020 (MM/DD/YYYY)			
Anticipated Arrival Time:	:: 20 ♥ 00 ♥ (24-hour clock HH:MM)			

- State: **Tennessee**
- Port code. CODE 2095
- Anticipated Arrival date: enter the **ship date + 1 day**
- Arrival time: enter 20:00 by default

#### 3- Submitter information

• Enter submitter's Name, Business Name, Full Address, phone number and email address

Web Entry: Submitter (Enter)		
Do one of the following to enter Submitter information:		
>> If you have the Submitter's Food Facility Registration Number, enter it along with the Facility Name and Cit	ty.	
>> If you do not have the Submitter's Food Facility Registration Number, enter at least all required items deno	ted by an asterisk (*).	
Food Facility Registration Number:	Find From Favorites	
*Business Name:	XXXX	
*Street Address:	XXXXXXX	
*City:	LYON	
Country Subdivision:	(state, province, etc.)	
*Country:	France Change Country	
ZIP/Mail Code:		
Enter the Submitter's Name, Phone, E-mail address. You may also provide the Fax Number, if available.		
*First Name:	XXXX	
*Last Name:	XXXXX	<u>Note:</u> don't check the box "add to
*Phone:	XXXXXXXX	my favorite list" if you do not have
Fax (OPTIONAL):		a "Tood facility registration number"
*E-mail:	XXXXXXX	
Add to my Favorite list		
	Save Cancel	

### 4-Importer information

 Enter the name and full address of the importer. In case the Importer is the submitter make sure that you check the box "Importer same Facility as Submitter"

### 5- Carrier information (if you ship with FedEx)

- Mode of Transportation: Express
   Courier Air
- IATA Code: **FX**
- Carrier Name: FedEx
- FedEx Airway bill or tracking Number (12 digits)



#### Your web entry is now completed, you can review the summary and Save

• Web Entry (Create)	
To create a new Web Entry, enter the information on this page and then click on the Save button. Required items	are marked with an asterisk (*).
Enter all Entry Information marked with an asterisk (*). If you do not have an Entry Identifier, leave the Entry Id	entifier blank and enable the Not Known checkbox to request the system to assign you one.
The Anticipated Port of Arrival and the Anticipated Arrival Date and Time are ontional for the Consumption. Expre	ses Courier entry type. This information should only be provided if it has been confirmed by express courier company.
*Entry Identifier:	▶ Not known. (Requests a system-generated identifier.)
*Entry Type:	Consumption, Express Courier
*How many Prior Notices do you or your company intend to submit for this Web Entry?	1
Port of Arrival	
Enter the Port Code for the Port of Arrival and the Arrival Date and Time. Please note if the Arrival Date and Time The time should be in the time zone of the Port of Arrival. If you do not know the Port Code, select the state and	is in the past then this Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Anticipated Arrival Date and Time. dick on the Find Port Code button.
Port:	TN (2095)
State:	Tennessee V Find Port Code
	OR Port Code: 2095
Anticipated Arrival Date:	11012021 (MM/DD/YYYY)
Anticipated Arrival Time:	20 V 00 V (24-hour dock HH:MM)
Submitter	Edit
XXXX	Registration Number:
XXXXXX LYON	Name: XXXXXX Phone: XXXXXX
FRANCE	Fax: e-mail: cecile.roio@fedex.com
Importer	Edit
delice roffee	Registration Number
Sth avenue	regioù den rumen.
UNITED STATES	
Carrier	Edit
Mode of Transportation: Express Courier - Air	Airway Bill or Tracking Number: 123456789123
Carrier Code (IATA): FX	
	Save Cancel
Diesee refrain from using your browser's BACK button while in the application process. Using your browser's BACI	/ hutton may result in your

### **Step 2: Create the Prior Notice - detailed product information**

You can now create the PN by clicking on the "Create Prior Notice" button at the bottom of the page.

nter all Entry Information marked with an asterisk (*). If you do not have an Entry Identifier, leave the Entry I	Identifier blank and enable the Not Known checkbo	to request the system to assign you one.
he Anticipated Port of Arrival and the Anticipated Arrival Date and Time are optional for the Consumption, Exp	ress Courier entry type. This information should on	y be provided if it has been confirmed by express courier company.
*Entry Identifier:		Not known. (Requests a system-generated identifier.)
*Entry Type:	Consumption, Express Courier	
*How many Prior Notices do you or your company intend to submit for this Web Entry?	1	
ort of Arrival		
nter the Port Code for the Port of Arrival and the Arrival Date and Time. Please note if the Arrival Date and Tim	ne is in the past then this Date and Time is consider	ed the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Anticipated Arrival Date
Port: Th		
State: T	ennessee V	Find Port Code
	P. Port Code: 2095	
Anticipated Arrival Date: 0	2/19/2021 (MM/DD/YYYY)	
Anticipated Arrival Time:	20 ▼ 00 ▼ (24-hour clock HH:MM)	
ubmitter		
XXXX		Registration Number:
xxxx 69000		Phone: XXXXXXXXXX
FRAINCE		e-mail: XXX.XXX@XXX.com
iporter		
DELICE COFFE 5 TH AVENUE NEW YORK, New York 10110 UNITED STATES		Registration Number:
arrier		
Mode of Transportation: Express Courier - Air		Airway Bill or Tracking Number: 123456789123

#### 6- Product Information

- Country from which the product is shipped
- FDA Product Code: You can either ask the manufacturer of the product or use the search functionality: choose Class and Group, Type of industry, Product Identifiers information.
- Product name: Common or Usual Name/Market Name

2 Prior Notice: Article (Create)
To create a Prior Notice, enter the Article information. You must enter or select a value for each item marked with an asterisk, "*". Entry Identifier: ###-3929192-5
*Country from which the Article is Shipped: France (FR)
Product Information
Enter the exact seven-character Product Code. Use the Search button to find the Product Code. Use "99", meaning "Not Elsewhere Classified", as the last two characters of the Product Code ONLY if a specific code for food does not exist.
*FDA Product Code: 33CAF05
FDA Product Description: CANDY BAR OR PIECES (NOT CARAMEL OR FONDANT), HARD, WITH FRUIT (WITHOUT CHOCOLATE), Fabric, Aseptic Pack
*Common or Usual Name/Market Name: CANDY BAR
Production Identifiers Add
Production Identifiers are the Lot Codes, Production Codes, or other identifiers associated with products. The production identifiers are mandatory if the product is required to bear such numbers by the FD&C Act or by FDA regulations. Use the Add and Delete buttons to add or remove Production Identifiers.

#### 7- Quantity and packaging information

- Measure Unit / Is it a Bulk-Shipment?
- For all other products, enter the base unit as the size of the smallest package.
- Quantity of food from largest container to smallest.

2 Prior Notice: Article (Create)		r,000 cases and each case
		contains 100 bags of candy
To create a Prior Notice, enter the Article information. You must enter or select a value for each item marked with Entry Identifier: ###	n an asterisk, "*". #-4190623-2	weighting 5 grs each, you would
*Country from which the Article is Shipped: Fran	ance (FR)	ontor 5 ars as the base unit
Product Information		enter 5 grs as the base unit
Enter the exact seven-character Product Code. Use the Search button to find the Product Code. Use "99", meaning	ng "Not Elsewhere Classified", as the last two characters of the Product Code ONLY if a specific code for	measure.
*FDA Product Code: 33C	CAF05 Search >>	
*Common or Usual Name/Market Name: CAN	NDY	Then enter 1,000 as the "Number"
Production Identifiers		and "cases" as "Package Type" on
Production Identifiers are the Lot Codes, Production Codes, or other identifiers associated with products. The products	oduction identifiers are mandatory if the product is required to bear such numbers by the FD&C Act or t	
Quantity and Packaging		the first line.
You may invoke the wizard to build the Quantity and Packaging for this Article by clicking on this but	tton. Wizard	On the second line you would
For packaged food, enter the weight or volume of the smallest (Base) unit. For, example, 16 "ounces, weight (ave information if the Bulk-shipment checkbox is checked. You must create a separate Prior Notice for each article of food with a different base unit.	/dp)", if the smallest unit is a 16 oz can. If the product has no packaging, enter the net weight or volun	enter, 100 as the "Number" and
*Base Unit (Number and Measure): 5	Grams 🔻 🗏 Bulk-shipment (no packages)	, hag as "Package Type
For packaged food, provide the estimated quantity of food that will be shipped, described from the largest contain	iner to smallest package size (up to five packaging levels may be provided). For example, 500 Cases, v	oug us Tuekuge Type.
Number	Package Type	
Largest Package to V 1000 Smallest Package	Case 🔻	Total Quantity: 500,000 Grams
▼ 100	Bag 🗸	Calculate
▼	▼	
▼	▼	
•	T	

Example: if the shipment contains

each case

#### 8- Product refusal information

• If the Article has been refused entry by any country / countries.

Note: "Save Prior Notice" button at the top or bottom right.

#### **Refusal Information**

This section only applies if the actual food in this current shipment (not previous shipments of the same food product) has been refused entry by any Country/Area, including the United States.



The "Save Prior Notice" page will display all the Web Entry and Prior Notice information for review and verification. Your Prior Notice will NOT be submitted to FDA when you save it, you must complete your web entry in order for your Prior Notice to be submitted. Selecting "No" will allow you to go back and edit your Prior Notice/Web Entry

			Web Ent	try Article Rel
otice: Related Facilities (View)				Copy
per have the ability to submit a Prior Notice until the a Prior	ir Web Entry is complete. Selectir Notice Confirmation number, you	g "Yes" will set your Prior Notice to "saved" must complete your Web Entry. Selecting no	tatus but will NOT submit this information to the FDA. In order to submit your saved Prior No vill allow you to go back and edit your Prior Notice/Web Entry.	otice(s) to FDA a
Entry Identifier: ###-419062	3-2		Article Number: 0001	
Manufacturer				
If the food is no longer in natural state, the FDA Country of Pro	oduction is generally the country where th	e food was made. Select the FDA Country of Production	from the drop-down list. Then, click on the Enter Manufacturer button.	
*FDA Co	untry of Production:	V	Enter Manufacturer	
Shipper				
Select the Country where the Shipper's business is located. Th	en, click on the Enter Shipper button.			
	*Country:	▼	Enter Shipper	
Owner				
Select the Country where the Owner's business is located. The	n, click on the Enter Owner button.			
	Country: United States (US	)	Enter Owner	
Ultimate Consignee				
The Ultimate Consignee of the imported article must have a va	lid physical address in the United States.	Click on the Enter Ultimate Consignee button to provide	information about the Ultimate Consignee.	
			Enter Ultimate Consignee	
Holding Facility (Required if this Prior Notice is Sub	omitted Post Refusal)			
If U.S. Customs and Border Protection (CBP) has directed	d this article to a Holding Facility, cli	k on the Enter Holding Facility button to provide	pecific information about the Holding Facility.	
			Enter Holding Facility	
				3 Sa

#### At the bottom of the page you may choose "Yes" to save or "No" to continue editing the Prior

#### Save Prior Notice?

STEP BY STE

Please verify that the information contained within your Web Entry and Prior Notice is correct to the best of your knowledge. Once your Prior Notice is saved, it will go into "Saved" status. You will have the opportunity to edit your saved Prior Notices(s) before submitting your Web Entry by going to the "Web Entry -View" page and selecting the Prior Notice that needs to be edited. Once you submit your Web Entry, you may no longer edit information in any of the Prior Notices associated with that Web Entry.

Transmitter: FedEx	
Web Entry	
Entry Identifier: ###-4190623-2	Status: Open
Port of Arrival: FedEx - Memphis, Memphis, TN (2	095)
Anticipated Arrival Date and Time: 02/19/2021 20:00	Entry Type: Consumption, Express Courier
Submitter	
XXXXX	Registration Number:
xxxx xxxx 69000	Name: XXX XXA Phone: XXXXXXXXXX
FRANCE	Fax: e-mail: XXX.XXX@XXX.com
Importer	
DELICE COFFE	Registration Number:
NEW YORK, New York 10110	
Carrier	
Mode of Transportation: Express Courier - Air	Airway Bill or Tracking Number: 123456789123
Carrier Name: FEDEX	
Article	
Article Nur	aber: 0001
FDA Country of Produ	tion: ()
Country from which the Article is Shi	ped: France (FR)
Product Information	
FDA Product (	iode: 33CAF05
FDA Product Descrip	tion: CANDY BAR OR PIECES (NOT CARAMEL OR FONDANT), HARD, WITH FRUIT (WITHOUT CHOCOLATE), Fabric, Aseptic Pack - Commercially Sterile
Production Identifiers	ine: Cardi
Quantity and Packaging	
Total Qua	ntity: 500,000 Grams
Base	Unit: 5 Grams
Packaging from largest to smallest pac	rage: 1,000 Case
	100 Bag
Refusal Information	
	USdi;
Related Facilities	
Manufacturer	
Shipper	
Owner	
Ultimate Consignee	
Holding Facility	
Article Not Held	
Users no longer have the ability to submit a Prior Notice until their Web Entry is complete	Selecting "Yes" will set your Prior Notice to "saved" status but will NOT submit this information to the FDA. In order to submit your saved Prior Notice(s) to FDA and
receive a Prior Notice Confirmation num	ber, you must complete your Web Entry. Selecting no will allow you to go back and edit your Prior Notice/Web Entry.

• Pay attention to the message in red. Your web entry must be complete in order for your Prior Notice to be submitted: manufacturer, shipper, owner, ultimate consignee information.

must correct the following before proceeding:					
The Manufacturer's Food Facility Registration Numl     Ultimate Consignee information is required Navigat	ber is Required. Please navigate to the Prior Notice: R te to the Prior Notice: Related Facilities (View) page to	elated Facilities (View) page and edit t	the Manufacturer.		
<ul> <li>Owner information is required. Navigate to the Prior</li> </ul>	r Notice: Related Facilities (View) page to add the Own	er information.			
<ul> <li>Snipper information is required. Navigate to the Price</li> <li>Manufacturer or Grower/Consolidator information is</li> </ul>	s required. Navigate to the Prior Notice: Related Facili	ipper information. ties (View) page to add the Manufactui	rer or Grower/Consolidator information.		
<ul> <li>Name and full address of the Shipper facility is required.</li> <li>Name and full address of the Owner facility is required.</li> </ul>	uired. Please navigate to the Prior Notice: Related Fac red. Please navigate to the Prior Notice: Related Facil	ilities (View) page and click on the Edi ties (View) page and click on the Edit	t button in the Shipper section to enter the r button in the Owner section to enter the rea	equired information. uired information.	
Name and full address of the Ultimate Consignee fa	cility is required. Please navigate to the Prior Notice:	Related Facilities (View) page and clic	k on the Edit button in the Ultimate Consign	ee section to enter the required information.	
Users no longer have the ability to submit a Pri	or Notice until their Web Entry is complete. Se	ecting "Yes" will set your Prior N	lotice to "saved" status but will NOT si	ubmit this information to the FDA. In order to submit you	r saved Prior Notice(s) to FD
Entry Identif	fier: ###-4190623-2	you must complete your web Lin	Article Number: 0001	ack and early our Phot Notice, web Entry.	
Manufacturer					
If the food is no longer in natural state, the	FDA Country of Production is generally the country where	the food was made. Select the FDA Cou	intry of Production from the drop-down list. Th	en, click on the Fater Manufactures button	
	*FDA Country of Production:	V		Enter Manufacturer	
Shipper					
Select the Country where the Shipper's busin	ness is located. Then, click on the Enter Shipper button.				
	*Country:	¥		Enter Shipper	
Owner					
Select the Country where the Owner's busin	ess is located. Then, click on the Enter Owner button.				
	Country: United States (U	S) 🔻		Enter Owner	
Ultimate Consignee					
The Ultimate Consignee of the imported artic	cle must have a valid physical address in the United State	s. Click on the Enter Ultimate Consignee	button to provide information about the Ultim	ate Consignee.	
				Enter Ultimate Consignee	
Holding Facility (Required if this Price	or Notice is Submitted Post Refusal)				
If U.S. Customs and Border Protection (	CBP) has directed this article to a Holding Facility,	click on the Enter Holding Facility bu	itton to provide specific information about	the Holding Facility.	
				Enter Holding Facility	

#### 9- Manufacturer information or grower/consolidator information

- Select the Country where the manufacturer's business is located. Then, click on the Enter Manufacturer button.
- Food Facility Registration Number: If you don't have it check the box "Manufacturer is not required to register or registration number is not known" and choose a "reason the registration number is not being provided"
- Name and Full Address of the manufacturer.

0	Prior Notice: Manufacturer	(Enter)
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The Product Code you entered indicates that the product is no longer in its natural state, meaning the art	ticle of food has been made from one or more ingredients or has been synthesized, prepared, treated, modified, or manipulated.
>> If the Manufacturer is required to register, enter the Manufacturer's Food Facility Registration Number via the Food Facility Registration Module (FFRM). You should contact the Manufacturer to get the app	er along with the Facility Name and the City to identify the Facility. The Registration Number is issued to the Manufacturer when the facility is registered with the Food and Drug Administration propriate Registration Number.
>> If the Manufacturer is not required to register or the manufacturer's registration number is not know appropriate; City; State or Province as appropriate; Zip/Mail Code, as appropriate; and Country.)	vn, enable the checkbox below, select the reason that the registration number is not being provided and provide the full address of the facility (Street Name and Number; Suite/Unit Number, as
* Food Facility Registration Number:	Find From Favorites
* Name:	
Street Address:	
* City:	
Country Subdivision:	▼ (state, province, etc.)
Country:	France (FR) Change Country
ZIP/Mail Code:	
	Manufacturer is not required to register or registration number is not known.
Reason the Registration Number is Not Being Provided.	Ψ
Should this Facility be the default Manufacturer for new Prior Notices for this Web Entry?	No V
Add to my Favorite list	Save

Please refrain from using your browser's BACK button while in the application process. Using your browser's BACK button may result in your having to re-enter the information.

#### 10-Shipper information

- Select the Country where the Shipper's business is located. Then, click on the Enter Shipper button.
- If the Shipper is the same as the Manufacturer, submitter or Importer you can use the field "Shipper same Facility as" and select the right option from the drop down list.
- If not, complete the name and full address and click on **"Save**".

2 Prior Notice: Shipper (Enter)	
If the Shipper is the same Facility as another that you have already entered facthin Scientification, whether	ill ignore any other data you enter for the Shipper.
Shipper same Facility as:	▼ Find From Favorites
Otherwise, do the following:	
>> Enter the Shipper's full address, (Street Name and Number; Suite/Unit Number, as appropriate; Cit	y; State or Province as appropriate; Zip/Mail Code, as appropriate; and Country.) You may also provide the Shipper's Food Facility Registration Number, if known.
Food Facility Registration Number:	
*Name:	
*Street Address:	
*City:	
Country Subdivision:	▼ (state, province, etc.)
*Country:	France Change Country
ZIP/Mail Code:	
Should this Facility be the default Shipper for new Prior Notices for this Web Entry?	No <b>T</b>
Add to my Favorite list	r's BACK button may result in your having to re-enter the information.

Follow the same process to complete the "Owner information" and the "Consignee Information".

#### 11- Holding facility

• Enter the "Holding Facility" information <u>only</u> if US Customs and Border Protection has directed this article to a holding facility.

Notice: Related Facilities (View)	Сору Са
nger have the ability to submit a Prior Notice until their Web Entry is complete. Selecting "Y FDA and receive a Prior Notice Confirmation number, you must	es" will set your Prior Notice to "saved" status but will NOT submit this information to the FDA. In order to submit your saved Prior Notic t complete your Web Entry. Selecting no will allow you to go back and edit your Prior Notice/Web Entry.
Entry Identifier: ###-4190623-2	Article Number: 0001
Manufacturer	
XXXX XXXX XXXX 101100 FRANCE	Registration Not Required Unable to determine the registration number of the manufacturer
Shipper	
Select the Country where the Shipper's business is located. Then, click on the Enter Shipper button.	
*Country: The Enter Second Sec	Shipper
Owner	
Select the Country where the Owner's business is located. Then, click on the Enter Owner button.	
Country: United States (US)	Owner
Ultimate Consignee	
The Ultimate Consignee of the imported article must have a valid physical address in the United States. Click o	in the Enter Ultimate Consignee button to provide information about the Ultimate Consignee.
Enter Ultima	te Consianee
Holding Facility (Required if this Prior Notice is Submitted Post Refusal)	
If U.S. Customs and Border Protection (CBP) has directed this article to a Holding Facility, click on t	the Enter Holding Facility button to provide specific information about the Holding Facility.
Enter Hold	ding Facility

All steps have now been completed, you can review the summary with the PN number that you will need to report on your commercial invoice.

Print the summary on the button at the bottom of the page, you can include it with your shipment documentation.

When you print the summary, you will get the following document to include to your shipment documentation:

## For more information you can refer to the <u>FDA website</u>.



# Thank You