

Farið er inn á síðuna <https://www.access.fda.gov/oa/>

Byrjað er á að stofna aðgang

NEW USER

- > **Create New Account**
- > See Instructions
- > See Tutorials
- > Help Desk

NEW ACCOUNT INFORMATION

You cannot use your Food Facility or Tobacco Registration and Product Listing account to register a Medical Device establishment. You must create a separate account to register your Medical Device establishment, Food facility and Tobacco Registration and Product Listing.

Select the systems you will need to access:

FDA Unified Registration Listing Systems

Food And Drug Facility Registration

Please select registration system(s)

Food Facility Registration

Acidified/Low-Acid Canned Foods Registration and Process Filing

Shell Egg Producer Registration

Other FDA Systems

Prior Notice System Interface (PNSI)

Device Registration And Listing

Tobacco Registration and Product Listing

Export Certification and Tracking Systems

CFSAN Export Certification and Tracking Systems

Certificate Application Process

Includes Landfood, Seafood, Cosmetics, Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods & Food for Special Dietary Use.

Biologics Export Certification Application and Tracking System

Biologics Export Certification Application & Tracking System

CONTINUE

CLEAR

CANCEL

Og fylla svo út í alla stjörnumerka reiti.

Þegar búið er að stofna aðgang og logga sig inn kemur þessi gluggi upp.. og valið er Prior Notice sem er alveg neðst á síðunni undir Other FDA Systems.

Welcome You are logged in as ██████████
Welcome to the FDA Industry Systems.

You are logged in to your account for company ██████████

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.

OTHER FDA SYSTEMS

> **Prior Notice of Imported Food**

Hér er valið Create New Web Entry, en ég mæli með að lesa texann sem á við.. góðar upplýsingar þar.

Welcome to the Prior Notice System Interface

The Prior Notice System Interface enables you to submit Prior Notices for Imported Food Articles to the Food and Drug Administration (FDA).

Get Started	▶ Overview of how to submit a Prior Notice for Food Importation.
Learn New Features	▶ Overview of New Features available in this version of the Prior Notice System Interface.
Create New Web Entry	<p>Creating a Web Entry is the first step in creating Prior Notices. A Web Entry contains information that one or more food articles you intend to import share (e.g., arrival information). After Creating a Web Entry, create, review, and submit Prior Notices. Prior Notices include information about the Product, its Quantity and Packaging, and other related information, such as the Manufacturer or Grower/Consolidator and the Shipper.</p> <p>You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. The system automatically "Completes" Web Entries with submitted Prior Notices when the Prior Notice submission timeframe elapses (see the "Complete Web Entry" Help topic).</p>
Find Existing Web Entry	▶ Use this feature to find Web Entries that you have already created.
Find Existing Prior Notice	▶ Use this feature to find Prior Notices that you have already created. To submit Holding Facility information for a Prior Notice submitted via PNSI by this account or another account within the same company, search for the Prior Notice and click the Submit Holding Facility button.
View/Submit Holding Facility	▶ To submit Holding Facility information for a Prior Notice that has been submitted via the U.S. Customs' and Border Protection (CBP) Automated Commercial System (ACS) or by another PNSI user of a different company click on the View/Submit Holding Facility button.
Manage Favorites	▶ Use this feature to maintain Favorite Facilities that you have already created.

Svo kemur þessi flettigluggi, þar á að velja Mail Non-commercial Sender, ef verið er að selja vöruna út skal velja Mail commercial sender, og klikkað á Next..

1 Web Entry (Create)

Select the Entry Type for the Web Entry and click on the Next button. Refer to the Help for the descriptions of the entry types.

*Entry Type:   Need Help?

Þá kemur þessi gluggi hér.. þegar allt hefur verið fyllt út skal valið Enter US Recipient

1 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 (*).

Entry Information

Enter all Entry Information marked with an asterisk (*).

*Entry Identifier: The system will generate an Entry Identifier for you when you save the Web Entry.


*Entry Type: Mail (Non-Commercial Sender)

*Anticipated Shipment Date:  (MM/DD/YYYY)

*How many Prior Notices do you or your company intend to submit for this Web Entry?


Submitter

The Submitter is the person with knowledge of the required Prior Notice information submitted to FDA. The Transmitter is the person who is logged into the system and who transmits the information either as the Submitter or on behalf of the Submitter. If you are the Submitter, answer Yes to the question below.

Are you the Submitter for this Web Entry? 

Hér er valið Yes ef sendandi er sá sami og sá sem skráður er fyrir aðgangi að síðunni, en No ef sendandi er annar og þá valið Enter Submitter


If you are NOT the Submitter, select the country containing the business location of the Submitter and then click on the Enter Submitter button to provide further information about the Submitter.

*Country: 

Hér er valið heimaland sendanda

United States Recipient

If the United States Recipient of the International Mail shipment is the same as the Submitter, answer Yes to the question below.

Is the United States Recipient the same as the Submitter?  Hér er valið No

If the United States Recipient is not the Submitter, click on the Enter US Recipient button to provide further information about the United States Recipient.

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

Og þá eru fylltar út upplýsingar um viðtakanda í Bandaríkjunum..

Það segir sig sjálft.. en aðeins er fyllt út reitirnir með stjörnu..

Því næst er valið Save

Þá er búið að skrá að maður ætli að senda pakka með matvælum í.

Þá er næsta skref að skrá upplýsingar um matvælin sem send eru.. þetta er gert fyrir hverja tegund fyrir sig

Þá velur maður Create Prior Notice

1 Web Entry (View) [Copy](#) [Copy Prior Notice From Another Web Entry](#) [Cancel](#)

This page displays all known information about the Web Entry. You may edit information in the Web Entry or its related facilities by clicking on the appropriate Edit button, if there are no submitted Prior Notices associated with it. To create a new Prior Notice, click on the Create Prior Notice option above.

Web Entry [Edit](#)

Entry Identifier: +++-4458162-0 Status: Open
Entry Type: Mail (Non-Commercial Sender)
Anticipated Shipment Date: 01/27/2010
Number of Intended Prior Notices: 1

Submitter [Edit](#)

Jonsdottir
Thingvallastraeti 18
Akureyri, Norðurland eystra 600
ICELAND

Registration Number:
Name: Bjorg Jonsdottir
Phone: 354-0-8232200
Fax:
e-mail: Dextxabmj@hotmail.com

United States Recipient [Edit](#)

Sarah Sertic
9467 Farifax Blvd. #203
Fairfax, Virginia 22031
UNITED STATES

Registration Number:

Prior Notices

None available.

[1 Create Web Entry](#) [2 Create Prior Notice](#)

Þá byrjum við bara efst og velju Iceland í felliglugganum, og nafnið á vörunni í Common or Usual Name, t.d. Ópal eða Nóa kropp (bara passa að hafa enga íslenska stafi) og svo Search í FDA Product Code

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: +++-4458162-0

*Country from which the Article is Shipped:

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: [Search >>](#)

*Common or Usual Name/Market Name:

Þá byrjar brasið..

Ég tek nammið Nizza frá Nóa sírius sem dæmi.. þá er skrifað Nizza í product Name

Og valið Choc/Cocoa Prod þar, sem þetta er súkkulaði (en valið er það sem passar helst fyrir hverja vöru), í fletti gugganum og svo next

Find Product Code

Either search for products or build Product Codes from their component parts.

Search

Find Product Codes by entering keywords and/or partial Product Codes and clicking on the Search button.

Product Name:

Product Code: Industry Class Group

Select Product Industry

Find Product Codes by selecting a Product Industry and clicking on the Next button.

Beverage Bases/Conc/Nectar - 30
Byproducts For Animal Foods - 71
Candy W/O Choc/Special/Chew Gum - 33
Cereal Prep/Breakfast Food - 05
Cheese/Cheese Prod - 12
Choc/Cocoa Prod - 34
Coffee/Tea - 31
Color Additiv Food/Drug/Cosmetic - 50

Svo er valin sú lýsing sem passar best við.. hægt er að þrengja valið í felli glugganum eða leita bara í öllum listanum..

Hér vel ég fyrir Nizza [CHOCOLATE CANDY BAR, WITHOUT NUTS AND FRUIT](#)

Find Product Code: Select Class

Select Product Classes or click on the appropriate Product Name in the Products column to complete the Product Code.

CHOC CANDY W/NUTS & FRUITS - G
CHOC CANDY WO/NUTS & FRUITS - F
CHOC/CHOC COV CANDY NUT PROD - C
CHOC/CHOC COV CANDY W/COCONUT - D
CHOC/CHOC COV CANDY W/FRUIT PROD - E
CHOC/COCOA - B
CHOC/COCOA BEVERAGE BASE - H
CHOC/COCOA PROD N.E.C. - Y

Products	Industry	Class	Group
BREAKFAST COCOA	34	H	01
BUTTERMILK CHOCOLATE (EXCEPT CHOCOLATE CANDY AND CHOCOLATE BEVERAGE BASE)	34	B	01
CHOC/CHOC COV CANDY NUT PROD SUCKER/NOVELTY	34	C	08
CHOCOLATE AND CHOCOLATE COVERED CANDY, WITH COCONUT, N.E.C.	34	D	99
CHOCOLATE AND CHOCOLATE COVERED CANDY, WITH FRUIT AND FRUIT PRODUCTS, N.E.C.	34	E	99
CHOCOLATE AND CHOCOLATE COVERED CANDY, WITH NUTS AND FRUIT, N.E.C.	34	G	99
CHOCOLATE AND CHOCOLATE COVERED CANDY, WITH NUTS OR NUT PRODUCTS, N.E.C. (NOT COCONUT)	34	C	99
CHOCOLATE AND CHOCOLATE COVERED CANDY, WITHOUT NUTS AND FRUIT, N.E.C.	34	F	99
CHOCOLATE AND COCOA BEVERAGE BASE, N.E.C.	34	H	99
CHOCOLATE AND COCOA PRODUCTS FOR BAKING, N.E.C.	34	K	99
CHOCOLATE AND COCOA PRODUCTS, N.E.C.	34	Y	99
CHOCOLATE AND COCOA, N.E.C.	34	B	99
CHOCOLATE BARS	34	K	04
CHOCOLATE CANDY BAR, WITH COCONUT	34	D	01
CHOCOLATE CANDY BAR, WITH FRUIT AND FRUIT PRODUCTS	34	E	01
CHOCOLATE CANDY BAR, WITH NUTS AND FRUIT	34	G	01
CHOCOLATE CANDY BAR, WITH NUTS OR NUT PRODUCTS (NOT COCONUT)	34	C	01
CHOCOLATE CANDY BAR, WITHOUT NUTS AND FRUIT	34	F	01
CHOCOLATE CANDY PIECES, WITH COCONUT	34	D	02

Þá er það bara umbúðir og meðhöndlun.. umbúðirnar hér eru plast en meðhöndlun er alltaf sú sama nema upplýsingar liggi fyrir á umbúðum vörunnar.

Find Product: Complete Product Definition

To complete the Product Code, select the Packaging Method and the Process Applied to the product and then click on the Select button.

Product Definition	
Product Name:	CHOCOLATE CANDY BAR, WITHOUT NUTS AND FRUIT
Industry:	34 = Choc/Cocoa Prod
Class:	F = CHOC CANDY WO/NUTS & FRUITS
Packaging Method (Subclass):	- = NONE SELECTED
Process Applied (Process Indicator):	- = NONE SELECTED
Group:	01 = CHOCOLATE CANDY BAR, WITHOUT NUTS AND FRUIT

*Packaging Method (Subclass):

- MULTIPLE CNTR - M
- NONFLEX PLASTIC - H
- NOT ELSEWHERE CLASSIFIED (NEC) - Y
- PAPER - F
- PLASTIC SYNTH - G
- VACUUM OR MODIFIED ATMOSPHERE PACKAGING - V
- WAX - W
- WOOD - J

*Process Applied:

- COMMERCIALY STERILE - E
- CULTURED/CURED - P
- HEAT TREATED - N
- IRRADIATED - R
- NOT ELSEWHERE CLASSIFIED (NEC) - Y
- NTRL/ARTFCL DRIED - H
- PACKAGED FOOD (NOT COMMERCIALY STERILE) - T
- PASTEURIZED - O

Þá erum við aftur komin hingað.. en þá er komið inn númer í FDA Product Code og kominn tími til að klára þessa síðu með því að setja inn þyngt og mælieiningu, Base Unit (number and Measure) og svo fjölda og í hvernig pakkningu.

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: +++-4458162-0

*Country from which the Article is Shipped:

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:

FDA Product Description: CHOCOLATE CANDY BAR, WITHOUT NUTS AND FRUIT, PLASTIC, SYNTH, NOT ELSEWHERE CLASSIFIED (NEC)

*Common or Usual Name/Market Name:

Production Identifiers

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.

Quantity and Packaging

You may invoke the wizard to build the Quantity and Packaging for this Article by clicking on this button.

For packaged food, enter the weight or volume of the smallest (Base) unit. For, example, 16 "ounces, weight (avdp)", if the smallest unit is a 16 oz can. If the product has no packaging, enter the net weight or volume as the Base Unit and check the Bulk-shipment checkbox. The system will ignore all Packaging 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.

*Base Unit (Number and Measure): ● ● Bulk-shipment (no packages)

For packaged food, provide the estimated quantity of food that will be shipped, described from the largest container to smallest package size (up to five packaging levels may be provided). For example, 500 Cases, with 40 Cans per Case (The weight of the individual can is the base unit).

	Number	Package Type	Total Quantity:
Largest Package to Smallest Package ▼ ●	<input type="text" value="1"/>	● <input type="text" value="Package"/>	
▼	<input type="text"/>	<input type="text"/>	<input type="button" value="Calculate"/>
▼	<input type="text"/>	<input type="text"/>	
▼	<input type="text"/>	<input type="text"/>	
▼	<input type="text"/>	<input type="text"/>	

●

Þá setjum við inn upplýsingar um framleiðanda þessarar vöru, að þessu sinni er það Nói siríus

Við byrjum á því að merkja að framleiðandinn er frá Íslandi og sendandi líka.. svo veljum við Enter Manufacturer

2 Prior Notice: Related Facilities (View) Copy Cancel PN

Entry Identifier: +++-4458162-0 Article Number: 0001

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 Country of Production from the drop-down list. Then, click on the Enter Manufacturer button.

*FDA Country of Production: Enter Manufacturer

Shipper

Select the Country where the Shipper's business is located. Then, click on the Enter Shipper button.

*Country: Enter Shipper

3 Submit Prior Notice

Þá eru fylltar út upplýsingarnar um Nóa, passa þarf að haka í kassann Manufacturer is not required... því ekki er hægt að finna Food Facility Registration Number, og í flettlugganum þar fyrir neðan hef ég valið K Unable to determine the registration number of the manufacturer, en þá þarf að fylla út fullt heimilisfang sendana, þ.e. bæta við götuheiti.. og svo er bara valið Save þegar allt hefur verið fyllt út

2 Prior Notice: Manufacturer (Enter)

The Product Code you entered indicates that the product is no longer in its natural state, meaning the article 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 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 via the Food Facility Registration Module (FFRM). You should contact the Manufacturer to get the appropriate Registration Number.

>> If the Manufacturer is not required to register or the manufacturer's registration number is not known, 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 appropriate; City; State or Province as appropriate; Zip/Mail Code, as appropriate; and Country.)

* Food Facility Registration Number: Find From Favorites

* Name:

Street Address:

* City:

Country Subdivision: (state, province, etc.)

Country: 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:

Should this Facility be the default Manufacturer for new Prior Notices for this Web Entry?

Add to my Favorite list

Save Cancel

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

Og þá er valið enter shipper.. sem er mjög einfalt..

2 Prior Notice: Related Facilities (View)

[Copy](#)[Cancel PN](#)

Entry Identifier: +++-4458162-0

Article Number: 0001

Manufacturer

[Edit](#)

Noi Sirius
Hesthalsi 2
Reykjavik, Reykjavik 110
ICELAND

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: Iceland (IS)

[Enter Shipper](#)[3 Submit Prior Notice](#)

Þá er bara valið í felliglugganum Shipper same facility as: Submitter ef að sendandi er sá sami og er skráður fyrir aðganginum að heimasíðunni.. annars eru bara fylltar út upplýsingar um sendanda og svo valið Save

2 Prior Notice: Shipper (Enter)

The Shipper is the person sending the international mail shipment. If the Shipper is the same as the Submitter, Transmitter, or US Recipient, select the applicable person and click on the Save button. Note: If you do this, the system will ignore any other data you enter for the Shipper.

Shipper same Facility as:

[Find From Favorites](#)

Otherwise, do the following:

Transmitter

Submitter

>> Enter the Shipper's full address, (Street Name and US Recipient Identification Number, as appropriate; City; 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: Iceland

[Change Country](#)ZIP/Mail Code:

Is the Shipper the same for other items in this Web Entry?

Yes Add to my Favorite list [Save](#)[Cancel](#)

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.

Þá er bara valið submit prior notice

2 Prior Notice: Related Facilities (View)

[Copy](#)[Cancel PN](#)

Entry Identifier: +++-4458162-0

Article Number: 0001

Manufacturer

[Edit](#)

Noi Sirius
Hesthalsi 2
Reykjavik, Reykjavik 110
ICELAND

Registration Not Required
Unable to determine the registration number of the manufacturer

Shipper

[Edit](#)

Shipper is same as the Submitter

[3 Submit Prior Notice](#)

Þá færðu yfirlit og getur breytt ef eitthvað er ekki rétt, og svo valið Yes neðst ef á að staðfesta að þetta sé rétt..

Þegar það er samþykkt færðu PN Confirmation Number: og svo nokkurra stafa númer..

Og ert beðin um að samþykkja að þetta sé rétt ef það er rétt er einfaldlega valið Yes

4 Complete Web Entry?

Prior Notice Submission Confirmed. Confirmation Number: 100108297531

You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection (CBP) to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. Completing the Web Entry indicates that you do not need to submit further Prior Notices for this Web Entry. It cancels all remaining draft Prior Notices and prevents you from submitting additional associated Prior Notices. After Completing the Web Entry, use the PN Confirmation Number(s) in the Prior Notices section on the Web Entry (View) page to annotate your Customs declaration. You may use the "Print Summary" button to print the Web Entry Summary Confirmation for your own records. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.279 (f)). If, after completing your Web Entry, you should become aware of substantive changes to the information in your Web Entry or Prior Notices (such as changes in product, or related facilities), you must resubmit the Prior Notice and should cancel the Web Entry or incorrect Prior Notices and then copy the Web Entry to make changes as appropriate. Changes to the Anticipated Arrival information, Estimated Quantity, or Planned Shipment information do not represent changes that require resubmission of Prior Notice.

The following Prior Notices have not been submitted and will be canceled upon completion of this Web Entry.

Article	Product	Create Date
No draft Prior Notices available.		

Are you ready to "Complete" your Web Entry?

Yes No

Og þá færðu upp staðfestinuna..

PN Confirmation Númerið þarf þá að vera skrifað á pakkann, merkt PN Confirmation Number: (svo númerið)

Gott er að setja þetta númer á fylgibréfið í sama glugga og innihaldslýsing er skrifuð, og á pakkann sjálfan.

Vonandi eru þetta skiljanlegar leiðbeiningar..