【米国経由用】事前申告番号 / Prior Notice Confirmation取得手順

下記の情報は予告なく変更される場合があります。

【推奨ブラウザー】

FDAは以下のブラウザーの利用を推奨しています。

Internet Explorer (version9.0)

Google Chrome (version49.0以降)

<MACのPCをご利用の場合>

互換性の問題によりエラーが発生すると確認しておりますのでご注意ください。

【ステップ1】

FDAのホームページ(http://www.access.fda.gov/)にアクセスし、「Log-in」をクリックする。

FDA Industry Systems

FDA Industry Systems (FIS) was created to facilitate making submissions to the U.S. Food and Drug Adminis and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003 6



【ステップ 2】

FDA Industry Systemsの画面で、アカウントID とパスワードを入力し、 一番下の「I understand」にチェックを入れ、「Login」をクリックして進む。

FDA Industry Systems

07/30/2015 See System maintenance between 3:00 a.m. EDT an

Existing account holde	ers, enter your account ID &
password. Account ID	
gacaguraa.	
	*
Password	
Undor 1911 C.C. 1001	anyona who makan a matarially
Unider 10 0.3.6. 1001	, anyone who makes a materially
false, fictitious, or frau	dutent statement to the 0.0.

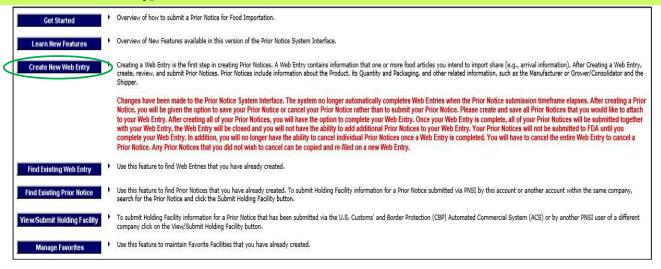
【ステップ3】

[Prior Notice system interface] をクリックする。

Other FDA Systems		
Prior Notice System Interface	チェックボックスを	ウリックできないので、文字部分をクリックする
☐ Import Trade Auxiliary Communication S	ystem (ITACS)	CBER Biological Product Deviation Reporting (CBER eBPDR)

【ステップ4】

「Create New Web Entry」 をクリックする。



【ステップ5】

Entry Typeで "Transportation and Exportation" を選択し、「Next」をクリックする。

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.

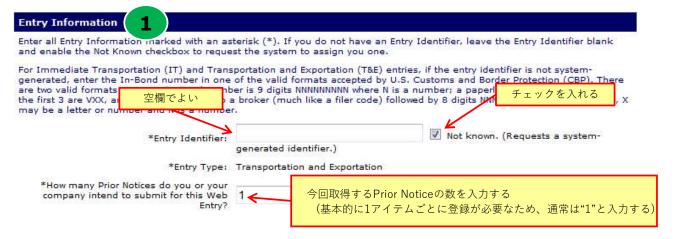


【ステップ 6】

次の画面の1~4に必要情報を入力し、「Save」をクリックする。

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 (*).



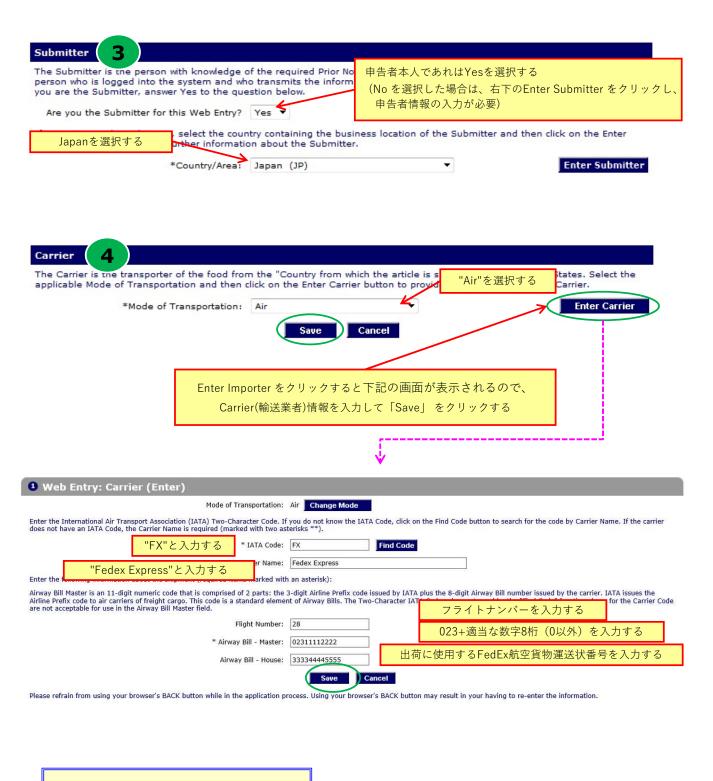
Port of Arrival

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 Anticipated Arrival Date and Time. The time should be in the time zone of the Port of Arrival. If 空港コードを入力する

Port:

State: **Find Port Code** ■アンカレッジ空港:3195 ■メンフィス空港:2095 OR *Port Code: 3195 フライト到着日(現地時間) ■オークランド空港:2895 (MM/DD/YYYY) al Date: 10/06/2014 ■インディアナポリス空港:4198 (24-hour clock *Anticipated Arrival Time: 11 ▼ 10 ▼ HH:MM) フライト到着時刻(現地時間/24時間表示)

> 空港コード・フライト到着日時につきましては、 カスタマーサービスにてご確認下さい。



フライトナンバーにつきましては、 カスタマーサービスにてご確認下さい。

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 (*). If you do not have an Entry Identifier, leave the Entry Identifier blank and enable the Not Known checkbox to request the system to assign you one.

For Immediate Transportation (IT) and Transportation and Exportation (T&E) entries, if the entry identifier is not system generated, enter the In-Bond number in one of the valid formats accepted by U.S. Customs and Border Protection (CBP). There are two valid formats: a paper In-Bond number is 9 digits NNNNNNNN where N is a number; a paperless In-Bond is 11 digits the first 3 are VXX, an identifier assigned to a broker (much like a filer code) followed by 8 digits NNNNNNNN where V is a letter, X may be a letter or number and N is a number.

	✓ Not known. (Requests a system-
generated identifier.)	
Transportation and Exportation	
1	
	Transportation and Exportation

Port of Arrival

Carrier Code (IATA): FX

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 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:	(3195)		
State:	[Find Port Code
	OR *Port Code:	3195	
*Anticipated Arrival Date:	10/06/2014	(MM/DD/YYYY)	
*Anticipated Arrival Time:	11 ▼ 10 ▼	(24-hour clock HH:MM)	

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? Yes ▼	
If you are NOT the Submitter, select the country co Submitter button to provide further information ab *Country/Area: Japa	then click on the Enter 修正したい箇所がある場合は、 該当項目の「Edit」をクリックする Enter Submitter
Carrier	Edit
Mode of Transportation: Air Carrier Name: FEDERAL EXPRESS	Flight Number: 28 Airway Bill - Master: 02311112222

Airway Bill - House: 333344445555 Save Cancel

【ステップ8】

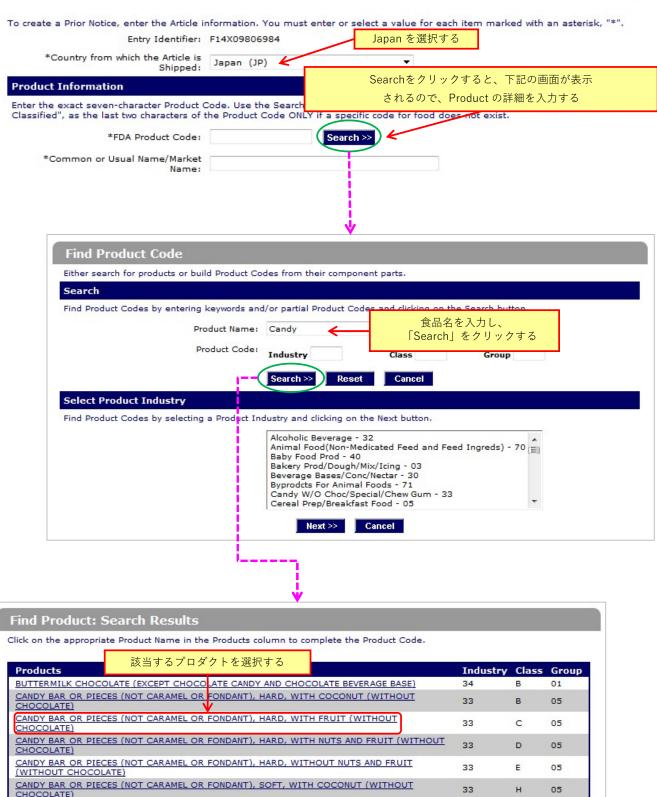
入力した情報の確認画面が出るので、訂正箇所がなければ右下の「Create Prior Notice」をクリックして次に 進む。



【ステップ9】

出荷国(Japan)を選択し、「Search」をクリックする。





Find Product: Complete Product Definition

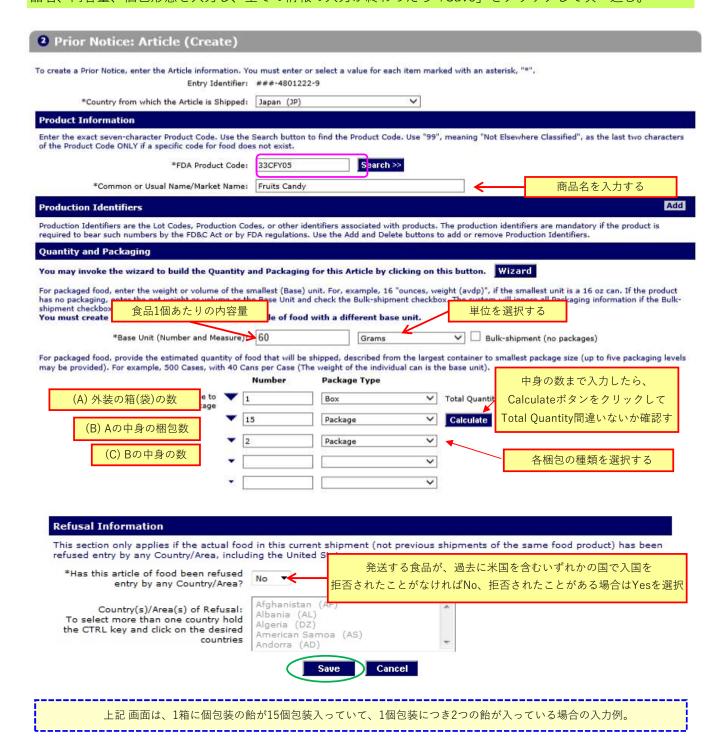
To complete the Product Code, select the Packaging Method and the Process Applied to the product and then click on the Select



- *ACIIFIED-I (酸化)
- *ASEPTIC PACK-F (無菌・防腐)
- *COMMERCIALLY STERILE-E(商業殺菌)
- *CULTURED/CURED-P(培養)
- *HEAT TREATED-N (熱処理)
- *IRRADIATED-R(放射能)
- *NOT ELSEWHERE CLASSIFIED(NEC)-Y (その他、どれにも該当しないもの)
- *NTRL/ARTFCL DRIED-H (天然/人工乾燥)
- *PACKAGED FOOD(NOT COMMERCIALLY STERILE) (包装済み食品/商用殺菌で ないもの) *PASTEURIZED-O (低温殺菌)
- *RAW, FRESH, FROZEN, NATURAL STATE-D (生、生鮮、冷凍、天然状態)
- *RAW, FRESH, AMBIENT-B (生、生鮮,室温)
- *RAW, FRESH, REFRIGERATED-C (生、生鮮、冷蔵)

【ステップ 11】

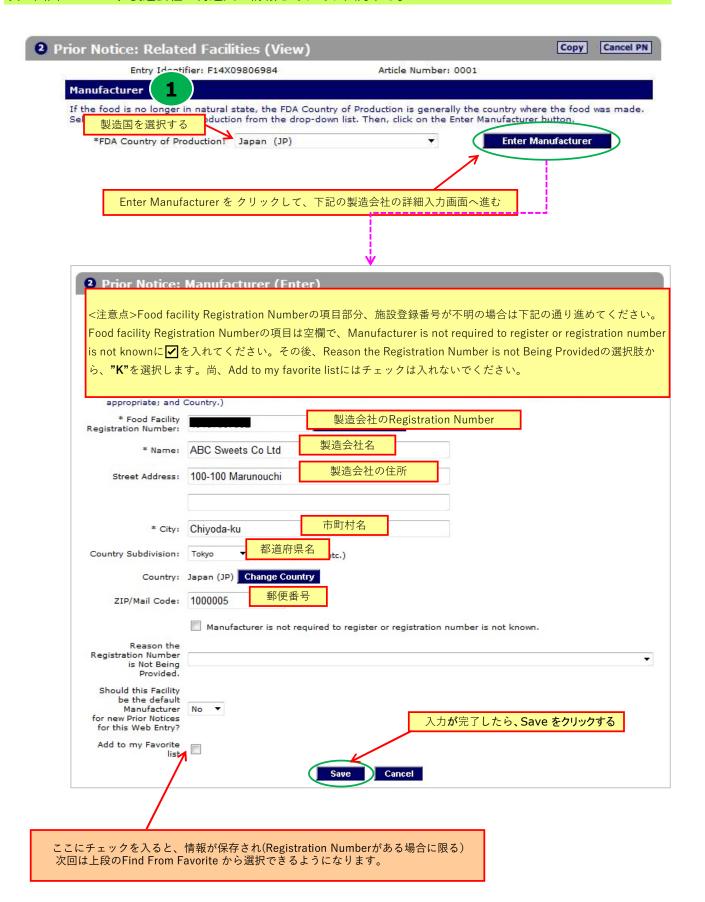
画面の表示が⑦に戻り、⑨で入力したFDA Product Codeが反映され(枠内参照)される。 品名、内容量、梱包形態を入力し、全ての情報の入力が終わったら「Save」をクリックして次へ進む。

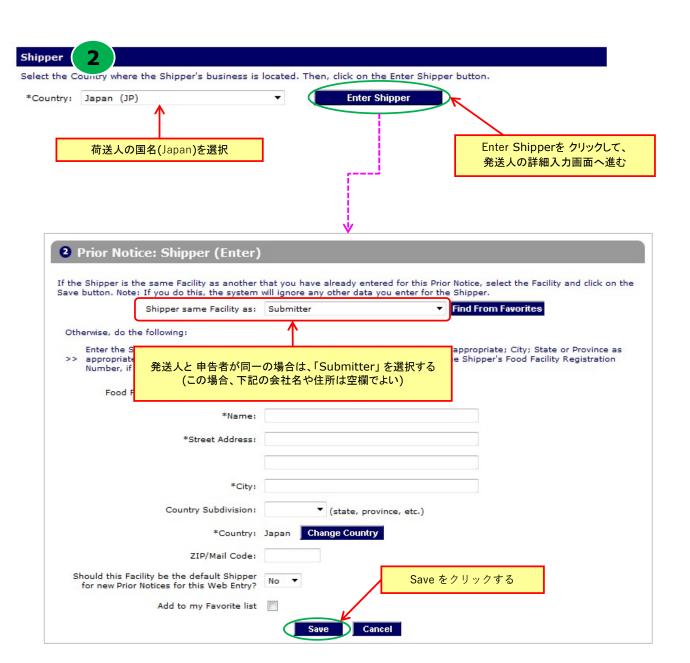


9

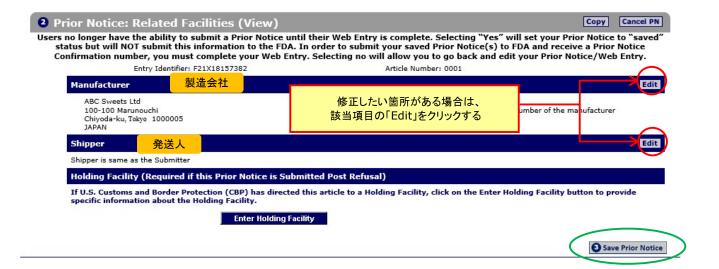
FedEx

次の画面の1~2で、製造会社・荷送人の情報をそれぞれ入力する。





⑬製造業者・発送人情報に訂正がなければ「Save Prior Notice | をクリックする。



3 Submit Prior Notice?

Please verify that the information contained within your Web Entry and Prior Notice is correct to the best of your knowledge. After you submit your first Prior Notice, you may no longer edit information in that Prior Notice or the associated Web Entry. Are you sure that you are ready to submit this Prior Notice?

Transmitter: FedEx



Entry Identifier: F14X09807046

Status: Open

FEDEX Anchorage, Anchorage, Port of Arrival:

AK (3195)

Anticipated Arrival Date and 10/06/2014 11:10

Transportation and

Entry Type: Exportation

Registration Number:

Export International Co Ltd 100-100 Marunouchi Chiyoda-ku, Tokyo 1000005 1APAN

Name: Phone: Fax:

Taro Yamada e-mail:

Mode of Air Transportation: FEDERAL EXPRESS Carrier Name: FX Carrier Code (IATA):

Flight Number: Airway Bill - Master: 02311112222 Airway Bill - House: 333344445555

Article

Article Number: 0001

FDA Country of Production: Japan (JP)

Country from which the Article is Japan (JP)

Shipped:

FDA Product Code: 33CFY05

CANDY BAR OR PIECES (NOT CARAMEL OR FONDANT), HARD, WITH FRUIT FDA Product Description: (WITHOUT CHOCOLATE), Paper, NOT ELSEWHERE CLASSIFIED (NEC)

Common or Usual Name/Market Name: Fruits Candy

Quantity and Packaging

Total Quantity: 30 Pieces

> Base Unit: 1 Pieces

Packaging from largest to smallest 1 Box

package:

15 Package

2 Package

Refusal Information

Country(s)/Area(s) of Refusal:

Related Facilities

ABC Sweets Co Ltd 100-100 Marunouchi Chiyoda-ku, Tokyo 1000005 JAPAN

Registration Number:

Shipper is same as the Submitter

Holding Facility

Article Not Held



⑤ Prior Noticeの確認画面が表示されるので、「Yes | をクリックする。

4 Complete Web Entry?

Your Prior Notices have NOT been submitted. Your Prior Notices will only be submitted to FDA when you have completed your 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, you should use the "Print Summary" button to generate the Web Entry Summary Confirmation that you should present to U.S. Customs and Border Protection (CBP) or the FDA at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (21 CFR 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 cancel your Web Entry which will cancel all attached Prior Notices. If your Web Entry has Prior Notices that need to be cancelled as well as Prior Notices that do not need to be cancelled, you must re-file the Prior Notices that do not need to be cancelled on a new Web Entry. Changes to the Anticipated Arrival information, Estimated Quantity, or Planned Shipment information do not represent changes that require cancellation of a Web Entry and resubmission of Prior Notice.

The following Prior Notices have not been saved 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?
Select Yes to complete your Web Entry
Select No to create additional Prior Notices or to edit your Web Entry and/or Prior Notices



⑯ 登録内容が表示されるので、右下の「Print Summary」をクリックする。

Web Entry (View)

Click on the Print Summary button to access the Web Entry Summary Confirmation. Print the Web Entry Summary Confirmation and present it to U.S. Customs and Border Protection or the Food and Drug Administration at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.279(f)).

Web Entry

Entry Identifier: F14X09807046

Port of Arrival: FEDEX Anchorage, Anchorage, AK (3195)

10/06/2014 11:10

Entry Type: Transportation and Exportation

Status: Completed

Copy

Cancel

Number of Intended Prior 1

Anticipated Arrival Date and

Notices:

Submitter

Export International Co Ltd 100-100 Marunouchi Chiyoda-ku, Tokyo 1000005 JAPAN Registration Number: Name: Taro Yamada

Phone: 81-3-12345678 Fax: e-mail:

Carrier

Mode of Transportation: Air Carrier Name: FEDERAL EXPRESS Carrier Code (IATA): FX Flight Number: 28 Airway Bill - Master: 02311112222 Airway Bill - House: 333344445555

Prior Notices

To view and work on any Prior Notice, click on the Article Number. To cancel Prior Notices, click on the applicable checkboxes and then click on the Cancel PN option.

Total Records Found: 1

Cancel PN						
	Article	Product	Status	Status Date	PN Confirmation Number	Submitted
	0001	Fruits Candy	Submitted	09/28/2014 22:31:43	140197312382	09/28/2014 22:31:43



Web Entry Summary Confirmation が出るので、プリントアウトして、航空貨物運送状、コマーシャルインボイスと合わせて貨物に添付する。

以上で手続きは完了となる。







Web Entry Summary Confirmation

Print this Web Entry Summary Confirmation and present it to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.279(f)).

WEB ENTRY

Envelope Number: F14X09807046

Entry Identifier: F14X09807046

Port of Arrival: FEDEX Anchorage, Anchorage, AK

(3195)

Entry Type: Transportation and Exportation

Anticipated Arrival: 10/06/2014 11:10

Mode of Transportation: Air

Number of Intended Prior Notices: 1

Submitter

Taro Yamada

Export International Co Ltd 100-100 Marunouchi Chiyoda-ku, Tokyo 1000005

JAPAN

Carrier

FEDERAL EXPRESS

Carrier Code (IATA): FX

Flight Number: 28

Airway Bill - Master: 02311112222 Airway Bill - House: 333344445555

PRIOR NOTICES

0001 Fruits Candy

JP

09/28/2014 22:31:43

140197312382

Confirmation Number (12 桁) は右下に表示されている *印刷の設定によっては数字が切れてしまうので、必ず12桁の表示を確認する

AWB 及びインボイスの品名欄には 「FS/T&E+品名+Confirmation Number」のように記入する。

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