# Food Facility Registration User Guide: Update Facility Registration

食品企业注册用户指南:

更新注册

Food Facility Registration User Guide: Update Facility Registration | FDA

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### Step 1 – Select the registration you want to

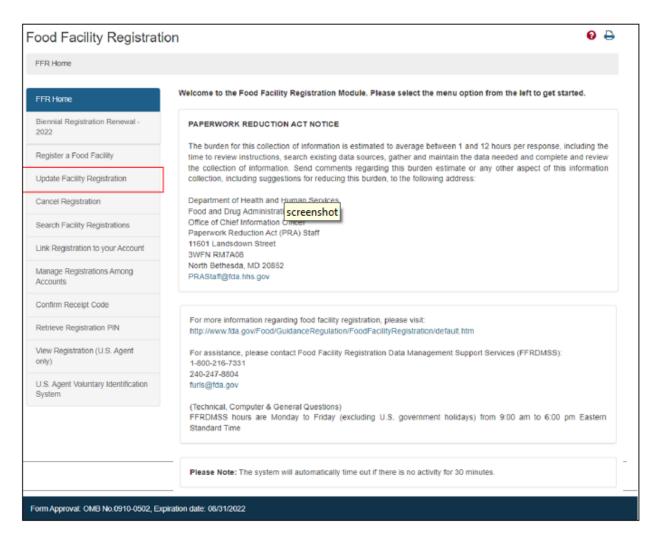
### 1步 - 选择您想更新的注册

Once you are logged in to FDA Industry Systems/your Online Account Administration (OAA) account, choose the "Food Facility Registration" (FFR) system. Next, choose the "Update Facility Registration" option from the FFR main menu (Figure 1).

用户在登录美国食品药品管理局(FDA)企业系统(FIS)/在线账户管理(OAA)账号后,选择"食品企业注册"(FFR)系统。接下来,在 FFR 主菜单选择"更新企业注册信息(Update Facility Registration)"选项(图 1)。

#### Figure 1 - FFRM Main Menu

#### 图 1- FFRM 主菜单



The system displays a list of all the registrations associated with the account (Figure 2). To choose a particular registration, select the hyperlinked Registration Number to view options for updating that registration.

系统会显示与该账户关联的所有注册的列表(图 2)。要选择某一个注册,选择带链接的注册号,查看更新注册的选项。

**Note:** Any registrations that are still due for renewal will not be displayed until you have successfully renewed them using the Biennial Renewal process.

注意: 任何需要延续的注册在您通过每两年延续注册流程成功延续之前都不会显示。

If you are the main account holder (i.e., the Enterprise account), this list includes all the registrations created by your Subaccounts. If you are a Subaccount holder, this list only includes the registrations that are linked to the Subaccount.

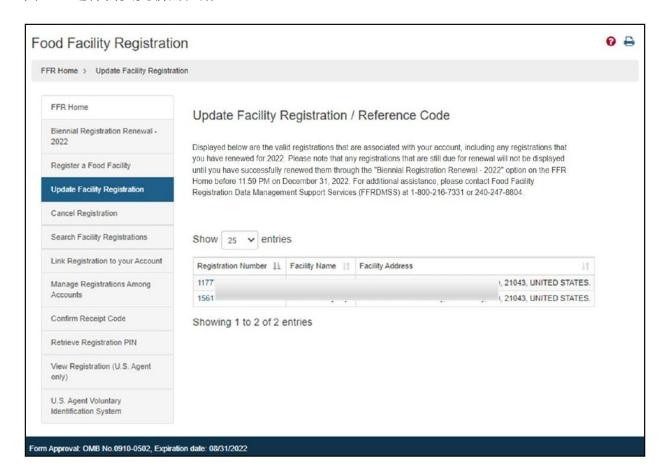
如果您是主账户所有者(即公司账户),该列表将包括您子账户所创建的所有注册。如果您是子账户所有者,列表只包含该子账户关联的注册。

**Note:** You will also be asked for Broker Identification questions if you are updating a registration that did not have this information captured when the registration was created. These questions will identify whether your facility needs to be registered (see the Registration of Food Facilities user guide for information).

**注意**:如果企业注册在创建时未包括企业是否是经销商的信息,那么在您更新注册时,您需要回答企业是否是经销商的问题。这些问题将明确您的企业是否需要注册(请参阅《食品企业设施注册用户指南》)。

#### Figure 2 - Select Registration to Update

#### 图 2 - 选择需要更新的注册



# Step 2 - Review the Registration

### 第2步-注册预览

If all the information is correct after review, select "Submit". You may also select "Cancel" to leave the Update process. The system displays a message that your registration was successfully updated.

如果检查后所有信息都是正确的,请选择"提交"。您也可以选择"取消"退出更新程序。系统会提示您的注册已成功更新。

If there is information that requires updating, continue to **Step 3 – Indicate which section of the registration you want to update.** 

如果有需要更新的信息,请继续第3步-选择注册需要更新的部分。

# Step 3 – Indicate which section of the registration you want to update

### 第3步-选择注册需要更新的部分

Sections that may be updated have an "Edit" button displayed on the registration review screen (Figure 3). Once you edit a section, you will need to navigate through all the application sections to submit any changes. Certain elements of the registration form are optional; updating those optional items is not required but is strongly encouraged. To modify the PIN for this registration, choose the "Modify PIN" link under Section 1.

在注册预览页面,可更新的部分会有"编辑(Edit)"按钮显示(图 3)。编辑某一部分后,您需要浏览完所有应用部分才能提交任何更改。注册表的有些内容是可选填的;对这些选填内容的更新无强制要求,但仍然建议进行更新。要修改注册的密码(PIN),请选择第 1 部分里的"修改密码(Modify Pin)"链接。

**Note:** The Facility Location information (which indicates whether the registration is a domestic or foreign facility) cannot be updated. If you wish to change the Facility Location information, you must create a new registration after cancelling the existing registration through the "Cancel Registration" main menu option.

**注意**:工厂位置信息(表明该注册是美国境内还是境外工厂的注册)是无法更改的。如果您想修改工厂位置信息,您必须通过主菜单"取消注册"选项取消现有注册后创建一个新的注册。

# Figure 3 - Registration Review Screen

## 图3-注册预览页面

✓ Section 1	✓ Section 2-4	✓ Section 5-7	✓ Section 8-9	✓ Section 9a-9b	✓ Section 10	✓ Section 11-12	Review
	ges to a sec			ion is correct on for that se Created by		Submit button	below. To
Created Date 2021-12-17 1				Registration Re	newed Date		
Registration I 2022-12-31	Expiration Date						
Last Updated 2021-12-17							
Registration S VALID	Status						
_	Status Reason Confirmation						
Is this facility en United States?	gaged in the ma	nufacturing/proc	essing, packing	, or holding of foo	od for human o	r animal consumption	in the
Yes   No							
Section 1:	Type of Re	egistration					
100000000000000000000000000000000000000	on : Domestic F		I: Registration	n Number:	Pin	No Mo	dify Pin
Are you the ne	ew owner of a pr	eviously register	red facility?				
⊚ Yes ○ No							
Previous Own		Number :					
Fiewous Own	ei s Regisii alion	radiliber .					
Section 2:	Facility Na	ame/Addres	ss Informat	tion			/ Edit
Facility Name	w Company			Telephone No 001 410 11			
Facility Name Company	Suffix			Fax Number			
Facility Name	Suffix Other			E-Mail Addre	ss		
Shop				Unique Facili	ty Identifier (U	FI)	
Facility Street	Address, Line 1				,		
Facility Street #D	Address, Line 2	2					
City Rockville							

# **Step 4 – Update the Facility Information**

# 第4步-更新企业信息

#### Section 2 - Facility Name / Address Information

第2部分-企业名称/地址信息

Update the facility name/address information.

更新企业名称/地址信息。

Field 内容	Description 说明
Facility Name 企业工厂名称	The name of the facility being registered. 注册的企业名称。
Facility Name Suffix 企业名称后缀	The type of company, for example, "company," "corporation," or "limited." 公司类型,如"company"、"corporation"或"limited"。
Facility Street Address, Line 1 工厂街道地址,第一行	The physical location of the facility being registered. This is normally a street address but may be some other physical/geographical designation used in rural locations. 注册的工厂的物理位置,一般是街道地址,但也有可能是农村地区的其他物理/地理地址。
Facility Street Address, Line 2 工厂街道地址,第二行	The second street name and address number, if applicable. May also enter information such as Suite number. 第二行街道名称和地址编号(如适用)。还可以输入房间号等信息。
City 城市	The city in which the facility is located. 工厂所在城市。
Country/Area 国家/地区	The country/area in which the facility is located. For foreign addresses, select a country/area from the pull-down menu. (For domestic registrations, United States is filled in automatically.) 企业工厂所在的国家/地区。如果是美国境外地址,请从下拉菜单选择一个国家/地区。(如果是美国国内企业的注册,系统会自动填入美国)。
State/Province/Territory 州/省/地区	The state, province, or territory in which the facility is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable." 企业工厂所在州/省/地区。从下拉菜单选择工厂所在州、省或地区,如果不适用请选择"不适用(Not Applicable)"。

Field 内容	Description 说明
Zip Code/Postal Code 邮政编码	The zip code (for domestic addresses) or postal code (for foreign addresses) of the facility being registered. 企业注册工厂的邮政编码。
Telephone Number: Country Code 电话号码: 国家区号	For foreign addresses, the three-digit country code of the telephone number for the facility being registered. 美国境外注册企业请输入工厂电话号码的三位数国家区号。
Telephone Number: Area Code 电话号码: 地区代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the facility being registered. 注册工厂电话号码中三位数字的地区代码(美国国内企业)或城市代码(美国境外企业)。
Telephone Number: Phone Number 电话号码	The telephone number of the facility being registered. 注册企业工厂的电话号码。
Phone Number: Extension 电话号码:分机号	The telephone extension, if any, dialed after the telephone number, of the facility being registered. 注册企业工厂的电话之后加拨的分机号(如有)。
Fax Number: Country Code (Optional) 传真号: 国家区号(选填)	For foreign addresses, the three-digit country code of the telephone number of the FAX machine for the facility being registered. 美国境外注册企业工厂传真号码的三位数字国家区号。
Fax Number: Area Code (Optional) 传真号: 地区号码(选填)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number of the FAX machine for the facility being registered. 注册企业工厂传真号码中三位数字地区代码(美国国内地址)或城市代码(美国境外地址)。
Fax Number: FAX Number (Optional) 传真号码(选填)	The telephone number of the FAX machine for the facility being registered. 注册企业工厂的传真号码。
E-mail Address 电子邮箱地址	An electronic mail address for the facility being registered. 注册企业的电子邮箱地址。
Confirm E-mail Address 确认电子邮箱地址	Confirm the email address entered. The E-Mails must match. 确认输入的电子邮箱地址。两次输入的电子邮箱地址必须匹配。
Unique Facility Identifier (UFI) 唯一企业设施识别码(UFI)	A Unique Facility Identifier (UFI) that allows users to identify the user's facility through a unique number such as a DUNS number. 唯一企业设施识别码(UFI),允许用户通过唯一编号(如 DUNS 编码)来识别用户的设施。

#### **Section 3 – Preferred Mailing Address Information**

#### 第3部分-首选邮寄地址信息

Update the Preferred Mailing Address Information. If the Preferred Mailing Address is the same as the Facility Address, you should leave this section blank. The Facility Address and the Preferred Mailing Address do not need to be in the same country/area.

更新首选邮寄地址信息。如果您企业的首选邮寄地址与企业工厂地址相同,则不应填写本部分。企业工厂地址和首选邮寄地址可以在不同的国家/地区。

Field 内容	Description 说明
Ticiu 114	Description (6.7)
AutoFill from Account Information 从账户信息自动导入	If this is the first facility registration entered by this account holder this session, this option will copy the company address data from your account information. Otherwise, this option will fill the address fields automatically using data in this section from the last registration entered this session. If you choose autofill and decide the information is not what you wanted, you may clear and enter the correct information manually.
	如果这是该账户第一次注册企业,该选项会从您的账户信息中直接导入企业地址信息。如果您的账户不是第一次注册企业,那么该选项会从您上次注册的企业信息中自动导入地址栏。如果您选择自动导入并认为导入的信息不是您想要填写的信息,您可以清除信息并手动输入正确的信息。
Name 名称	The name of the person or company where you wish to receive mail from FDA regarding this registration.
Street Address, Line 1	您希望接收 FDA 关于此次注册的邮件的个人或公司的名称。 The mailing address of the company or person named - the address at which you
 街道地址第一行 	would like to receive notices from FDA about this registration. 以上所列公司或个人的邮寄地址一您希望接收 FDA 关于此次注册的通知的地址。
Street Address, Line 2 (Optional)	The second street name and address number, if applicable. May also enter information such as Suite number.
 街道地址第二行 (选填)	第二个街道名称和地址号码(若适用)。还可以输入其他信息如门牌号码。
City 城市	The city in which the preferred mailing address is located.
	首选邮寄地址的城市。
Country/Area	The country/area in which the preferred mailing address is located. Select a country/area from the pull-down menu.
国家/地区	首选邮寄地址的国家/地区。请从下拉菜单中选择国家/地区。

Field 内容	Description 说明
State/Province/Territory 州/省/地区	The state, province, or territory in which the preferred mailing address is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."
	首选邮寄地址的州、省或地区。从下拉菜单选择工厂所在州、省或地区,如果不适用请选择 "Not applicable"。
Zip/Postal Code	The zip code (for domestic addresses) or postal code (for foreign addresses) for the preferred mailing address.
邮政编码	首选邮寄地址的邮政编码。
Phone Number: Country Code (Optional)	For foreign addresses, the three-digit country code of the telephone number for the preferred mailing address.
电话:国家区号(选填)	首选邮寄地址电话号码的三位数字的国家区号(美国境外地址)。
Phone Number: Area/City Code (Optional)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the preferred mailing address.
电话: 地区/城市代码	首选邮寄地址电话号码中三位数字的地区代码(美国境内企业)或城市代码(美国境外企业)。
(选填)	
Phone Number: Phone Number (Optional)	The telephone number for the preferred mailing address.
电话号码(选填)	首选邮寄地址的电话号码。
Phone Number: Extension (Optional)	The telephone extension, if any, dialed after the telephone number, for the preferred mailing address.
电话号码:分机号(选填)	首选邮寄地址电话如果有分机号,请填写分机号。
FAX Number: Country Code (Optional)	For foreign addresses, the three-digit country code for the telephone number of the FAX machine for the preferred mailing address.
传真号码:国家区号(选填)	海外注册企业首选邮寄地址传真号码的三位数字国家区号。
FAX Number: Area/City Code (Optional)	The three-digit area code (for domestic addresses) or city code (foreign addresses) of the telephone number of the FAX machine for the preferred mailing address.
传真号码:地区/城市号码 (选填)	首选邮寄地址传真号码中三位数字的地区代码(美国境内企业)或城市代码(美国境外企业)。
FAX Number: FAX Number (Optional)	The telephone number of the FAX machine for the preferred mailing address.
传真号码(选填)	首选邮寄地址的传真号码。
E-mail Address (Optional)电子邮箱(选填)	An electronic mail address for the preferred mailing address.
G (B = 41 :	首选邮寄地址的电子邮箱地址。
Confirm E-mail Address (Optional)	Confirm the email address entered. The E-Mails must match.
确认电子邮箱(选填)	确认输入的电子邮箱地址,两次输入的电子邮箱地址必须一致。

#### **Section 4 – Parent Company Name / Address Information**

#### 第 4 部分 - 总公司名称/地址信息

Update the Parent Company Name / Address Information. The company that owns the facility being registered is referred to as the Parent Company. If the Facility and the Parent Company have different names, you must complete this section; if they have the same name, leave this section blank. The Facility Address and the Parent Company Address do not need to be in the same country/area.

更新总公司名称/地址信息。拥有注册企业工厂所有权的公司是总公司。如果企业工厂名称和总公司名称不同,您必须完成该部分内容的填写;如果企业工厂名称和总公司名称相同,该部分不要填写。企业工厂地址和总公司地址可以在不同的国家/地区。

Field 内容	Description 说明
If information is the same as another section, check which	Specifies whether the parent company name/address information is identical to previously entered information. If you choose an option but decide the information is not what you wanted, you may clear and enter the correct information manually.
section 如果输入信息与其他已 填写部分的信息相同, 请检查与哪一部分相同	确认总公司名称/地址信息是否与之前输入的信息相同。如果您选择一个选项,但确定默认填入的信息不是您想输入的信息,您可以清除已填入信息并手动输入正确信息。  Choose Section 2 if the parent company name/address is the same as the facility name/address information entered in Section 2: Facility Name / Address Information.  如果您总公司名称/地址与您在第二部分输入的"企业名称/地址信息"一致,请选择第二部分。  Choose Section 3 if the parent company name/address is the same as the preferred mailing address information entered in Section 3: Preferred Mailing Address Information.  如果您总公司名称/地址与您在第三部分输入的"首选邮寄地址信息"一致,则选择第三部分。  Choose None of the Above if your Parent Company name address is different from the Facility and the Preferred Mailing Addresses  如果您总公司名称/地址与之前输入的企业名称及地址和首选邮寄地址都不相同,请选择"None of Above"
Clear	Select the "Clear" button if you need to clear Section 4
清除	如果您需要清除第四部分中所填信息,请选择"Clear"选项。

Field 内容	Description 说明
AutoFill from Account Information 从账户信息自动导	If this is the first facility registration entered by this account holder this session, this option will copy the company address data from your account information. Otherwise, this option will fill the address fields automatically using data in this section from the last registration entered this session. If you choose to autofill but decide the information is not what you wanted, you may clear and enter the correct information manually. 如果这是该账户第一次注册企业,该选项会从您的账户信息中直接导入企业地址信息。如果您的账户不是第一次注册企业,那么该选项会从您上次注册的企业信息中自动导入地址栏。如果您选择自动导入但认为导入的信息不是您想要填写的信息,您可以清除信息并手动输入正确的信息。
Company Name 企业名称	The name of the company that owns the facility being registered, if different from the Facility Name.  注册企业工厂所有者公司的名称(如果与企业工厂名称不同)。
Company Name Suffix 企业名称后缀 Street Address, Line 1 街道地址第一行	The type of company, for example "Company," Corporation," or "Limited." 企业类型,例如 "Company"、"Corporation"或"Limited"。  The address of the parent company. This can be a physical/geographical location or other mailing address. 总公司的地址,可以是物理/地理位置或其他邮寄地址。
Street Address, Line 2 街道地址第二行	The second street name and address number, if applicable. May also enter information such as Suite number.  第二个街道名称和地址号码(若适用)。还可以输入其他信息如门牌号码。
City 城市	The city in which the parent company is located. 总公司所在城市。
Country/Area 国家/地区	The country/area in which the parent company is located. 总公司所在国家/地区。
State/Province/Territor y 州/省/地区	The state, province, or territory in which the parent company is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable." 总公司所在州、省或地区。从下拉菜单选择工厂所在州、省或地区,如果不适用请选择"Not applicable"。
Zip/Postal Code 邮政编码	The zip code (for domestic addresses) or postal code (for foreign addresses) for the parent company.

Field 内容	Description 说明
Telephone Number— Country (Optional)	For foreign registrations, the three-digit country code of the telephone number for the parent company.
电话—国家区号(选填)	海外注册企业输入三位数字的总公司所在国家的电话区号。
Telephone Number— Area (Optional)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the parent company.
电话—地区代码(选填)	总公司电话号码中三位数字的地区代码(美国境内企业)或城市代码(美国境外企业)。
Telephone Number—	The telephone number of the parent company.
Phone Number (Optional)	总公司的电话号码。
企业电话号码(选填)	
Telephone Number— Extension (Optional)	The telephone extension, if any, dialed after the telephone number, of the parent company.
电话号码—分机号	总公司电话如果有分机号,请填写分机号。
(选填)	
FAX Number—Country (Optional)	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the parent company.
传真号码—国家区号(选填 )	海外注册总公司传真号码的三位数字国家区号。
FAX Number—Area (Optional)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the FAX machine of the parent company.
传真号码—地区号码(选填)	总公司传真号码中三位数字的地区代码(美国境内企业)或城市代码(美国境外企业)。
FAX Number—FAX	The telephone number of the FAX machine of the parent company.
Number (Optional) 传真号码(选填)	总公司的传真号码。
E-mail Address	An electronic mail address for the parent company.
电子邮箱	总公司的电子邮件地址。
Confirm E-mail	Confirm the email address entered. The E-Mails must match.
Address (Optional) 确认电子邮箱(选填)	确认输入的电子邮箱地址,两次输入的电子邮箱地址必须一致。

#### **Section 5 – Facility Emergency Contact Information**

#### 第5部分一企业紧急联系信息

Update the Facility Emergency Contact Information. FDA will use this information in case of emergency to notify the facility of the nature of the emergency. Unless foreign facilities choose to designate another emergency contact, FDA will use their U.S. agent as the emergency contact.

更新企业紧急联系信息。紧急情况下 FDA 会使用此信息通知企业。除非境外注册企业选择指定另外的紧急联系人,FDA 一般会用该企业的美国代理作为紧急联系人。

Field 内容	Description 说明
AutoFill from Account Information 从账户信息自动导入	If this is the first facility registration entered by this account holder this session, this option will copy the company address data from your account information. Otherwise, this option will fill the address fields automatically using data in this section from the last registration entered this session. If you choose to autofill but decide the information is not what you wanted, you may clear and enter the correct information manually. 如果这是该账户第一次注册企业,该选项会从您的账户信息中直接导入企业地址信息。如果您的账户不是第一次注册企业,那么该选项会从您上次注册的企业信息中自动导入地址栏。如果您选择自动导入但认为导入的信息不是您想要填写的信息,您可以清除信息并手动输入正确的信息。
Individual's Name 个人姓名	The first name and last name (surname) of the person to contact in case of emergency for the facility being registered. 该注册企业在紧急情况下联系人的姓名。
Job Title 职务	The job title for the emergency contact. 紧急联系人的职务。
Emergency Contact Phone: Country Code 紧急联系电话: 国家区号	For foreign registrations, the three-digit country code for the telephone number of the person or entity that FDA can call 24 hours a day, 7 days a week, in case of emergency. 对于美国境外注册企业,FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的个人或者单位电话的三位数字的国家区号。
Emergency Contact Phone: Area/City Code 紧急联系电话: 地区/城市 代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the telephone number of the person or entity that FDA can call 24 hours a day, 7 days a week, in case of emergency.  FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的个人或者单位电话号码的三位数字地区代码(美国国内企业)或城市代码(美国境外企业)。
Emergency Contact Phone: Phone Number 紧急联系电话: 电话号码	The telephone number of the person or entity that FDA can call 24 hours a day, 7 days a week, in case of emergency. FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的个人或者单位的电话。

Field 内容	Description 说明
Emergency Contact Phone: Extension 紧急联系电话: 分机号码	The telephone extension, if any, dialed after the telephone number of the person or entity that FDA can call 24 hours a day, 7 days a week, in case of emergency. FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的个人或者单位电话后加拨的分机号码(如适用)。
E-mail Address 电子邮箱地址	The electronic mail address for the emergency contact. 紧急联系人的电子邮箱地址。

#### **Section 6 - Trade Names**

#### 第6部分一商业名称

If this facility conducts business under a name other than that entered in Section 2: Facility Name / Address Information then complete this section. For example, complete this section if you describe your facility as "also doing business as ..." or "facility also known as ..."

如果企业在贸易过程中使用的名称不同于"第2部分:企业名称/地址信息"中填写的企业名称,那请完成此部分。例如,如果您描述您的企业为"贸易中还使用......(企业名称)"或"该企业还被称作......",则请填写此部分。

#### Fields Included in this Section 本部分需要填写的内容

Field 内容	Description 说明
Alternate Trade Name	A trade name other than that listed in Section 2: Facility Name / Address Information.
另外的商业名称	不同于"第2部分:企业名称/地址信息"中填写的企业名称的商业名称。

#### **Section 7 – United States Agent**

#### 第7部分 — 美国代理

Foreign facilities may update information about the United States Agent for the facility being registered. Every foreign facility must have a U.S. Agent who acts as the domestic communications representative for that facility. If you indicated in Section 1: Type of Registration, that the facility being registered is a foreign facility, you are required to enter information about the U.S. Agent. Domestic facilities do not require a U.S. Agent.

美国境外企业可以更新所注册企业的美国代理的信息。每个美国境外企业都必须有一个美国代理来作为该企业美国境内沟通的代表。如果在您在"第1部分:注册类型"中选择所

注册企业是美国境外企业,则您需要填写美国代理信息。美国境内企业不要求必须有美国代理。

**Note:** The U.S. Agent should not be confused with the Agent in Charge, which is another type of submitter for either domestic or foreign facilities.

**注意**: 不应把美国代理与负责代理人混淆。负责代理人是 美国境内外企业的另一种类型的提交人。

Field 内容	Description 说明
AutoFill from Account Information 自动导入账户信息	If this is the first facility registration entered by this account holder this session, no data will be entered. Otherwise, this option will fill the address fields automatically using data in this section from the last registration entered this session. If you choose to autofill but decide the information is not what you wanted, you may clear and enter the correct information manually.  如果这是该账户第一次注册企业,将没有数据输入。如果您的账户不是第一次注册企业,那么该选项会把您上次注册企业信息自动导入地址栏。如果您选择自动导入并认为导入的信息不是您想要填写的信息,您可以清除信息并手动输入正确的信息。
Please select (Yes) if new U.S. Agent is being reassigned. 如果指定新的美国代理,请 选"是(Yes)"	Choose one of the following two options: Yes. Registration number and PIN will be mailed to your new U.S. Agent or - No. Continue updating this section 从以下两个选项中选择: "是 (Yes)",注册号和密码会邮寄给您新的美国代理。 -或- "否 (No)",继续更新该部分。
Are you an individual, partnership, corporation, or association?	Select the option that best describes the U.S. Agent type. 请选择最符合美国代理类型的选项。
您是个人、合伙企业、公司、还是协会?	
Name of U. S. Agent 美国代理人姓名	The first name and last name (surname) of the person acting as U. S. Agent for the foreign facility being registered. 美国境外注册企业美国代理联系人的姓氏和名字。
Title (Optional) 职务(选填)	The job title of the U. S. Agent. 美国代理联系人的职务。
First Name 名字	The first name of the person acting as U. S. Agent for the foreign facility being registered. 海外注册企业美国代理人的名字。

Field 内容	Description 说明
Middle Name 中间名	The middle name of the person acting as U.S. Agent for the foreign facility being registered.
111074	海外注册企业美国代理人的中间名。
Last Name	The last name of the person acting as U.S. Agent for the foreign facility being registered.
姓氏	海外注册企业美国代理人的姓氏。
Country/Area 国家/地区	The country/area in which the U.S. Agent is located. Because the U.S. Agent must reside in the U.S., the Country/Area is automatically filled in with "United States."
,,,,,===	美国代理所在的国家/地区。因为美国代理必须居住在美国,所以国家/地区栏自动填入 "United States美国"。
Street Address, Line 1	The U. S. address of the U. S. Agent.
街道地址,第一行	美国代理的美国国内地址。
Street Address, Line 2 街道地址,第二行	The second street name and address number, if applicable. May also enter information such as Suite number.
M-6-25-11	第二个街道名称和地址号码(如适用)。还可以输入其他信息例如门牌号码。
City 城市	The city in which the U. S. address of the U.S. Agent is located. 美国代理地址所在的美国城市名称。
State 州	The state in which the U. S. address of the U.S. Agent is located. 美国代理地址所在州的名称。
Zip Code 邮政编码	The zip code for the U. S. address of the U. S. Agent. 美国代理所在地址的邮编。
U. S. Agent Phone Number: Area Code 美国代理电话号码: 地区代 码	The three-digit area code of the telephone number for the U. S. Agent. 美国代理电话号码的三位数字地区代码。
U. S. Agent Phone Number: Phone Number 美国代理电话号码	The telephone number for the U. S. Agent. 美国代理的电话号码。
U. S. Agent Phone Number: Extension 美国代理电话号码:分机号	The telephone extension, if any, dialed after the telephone number, for the U. S. Agent. 美国代理电话号码后加拨的分机号(如有)。
Emergency Contact Phone Number: Area Code 紧急联系人电话号码: 地区 代码	The three-digit area code of the telephone number for the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency. FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的美国代理电话的三位数字地区代码。

Field 内容	Description 说明
Emergency Contact Phone Number: Phone Number 紧急联系人电话号码	The telephone number for the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency. FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的美国代理的电话。
Emergency Contact Phone Number: Extension 紧急联系人电话号码:分机 号	The telephone extension, if any, dialed after the telephone number for the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency. FDA 在紧急情况下一周 7 天、一天 24 小时都可以联系到的美国代理电话的分机号(如有)。
FAX Number: Area Code 传真号码: 地区代码	The three-digit area code of the telephone number of the FAX machine for the U. S. Agent. 美国代理的传真号码的三位数字地区代码。
FAX Number: FAX Number 传真号码	The telephone number of the FAX machine of the U. S. Agent. 美国代理的传真号码。
E-mail Address 电子邮箱地址	The electronic mail address for the U. S. Agent. 美国代理的电子邮箱地址。
Confirm E-mail Address (Optional) 确认电子邮箱(选填项)	Confirm the email address entered. The E-Mails must match. 确认输入的电子邮箱地址,两次输入的电子邮箱地址必须一致。

#### **Section 8 - Seasonal Facility Dates of Operation**

#### 第8部分一企业的季节性运营日期

Dates of operation refer to the months during which the facility is open for business. If this facility operates on a seasonal basis, you may choose to complete this section. You might enter, for example, March - September.

运营日期是指企业工厂生产运营的月份。如果企业的生产运营有季节性,您可以选择填写此部分。您可以输入,例如: 3-9月。

#### Fields Included in this Section 本部分需要填写的内容

Field 内容	Description 说明
Dates of Operation For Harvest 1	The approximate months during which the facility operates, if it operates on a seasonal basis.
第一个采收时段的运营日 期	如果企业工厂是季节性运营的,其运营的大致月份。
Dates of Operation For Harvest 2	The approximate months during which the facility operates, if it operates on a seasonal basis. Select Start Month and End Month.
第二个采收时段的运营日 期	如果企业工厂是季节性运营的,其运营的大致月份。 选择开始月份和结束月份。

#### Section 9 - General Product Categories - Human/Animal/Both

第9部分 — 一般产品类别-人用食品/动物食品/人用食品和动物食品均有

Based on your facility's activities, you may choose Food for Human Consumption and/or Food for Animal Consumption.

根据您企业工厂的活动,您可以选择您的产品是供人食用和/或供动物食用。

# Section 9 (a/b) – General Product Categories – Food for Human/Animal/Both Consumption; and Type of Activity Conducted at the Facility

第 9 (a/b) 部分—一般产品类别-人用食品/动物食品/人用食品和动物食品均有;以及企业设施的活动类型

All facilities being registered must complete this information. Select as many categories as appropriate.

所有注册企业必须完成此部分内容的填写。填写时请尽量全面地选择产品类别。

**Note:** For more information about each of the categories included in Sections 9a and 9b, see the Product Code Builder and the relevant regulation (21 CFR 170.3).

**注意**: 有关第 9a 部分和第 9b 部分中包含的每个类别的更多信息,请参见产品代码生成器(Product Code Builder)和相关法规(21 CFR 170.3)。

#### Section 10 - Owner, Operator, or Agent in Charge Information

#### 第10部分 - 所有者、经营者或负责代理人信息

If the contact information for the owner, operator, or agent in charge is the same as that in another section of the form, select the appropriate option for that section; otherwise enter the information as requested.

如果所有者、经营者或负责代理人的联系方式信息与本表的其他部分相同,请选择与之相对应的选项;否则请按要求填写信息。

Field 内容	Description 说明
Name of Entity or Individual who is the Owner, Operator, or Agent in Charge 所有者、经营者或负责代理 人的名称(机构)或姓名 (个人)	The name of the person or entity who is the owner, operator, or agent in charge of the facility being registered. 注册企业的所有者、经营者或负责代理人的名称(机构)或姓名(个人)。
If information is the same as another section of the form, check which section 如果该信息与本表中其他部分相同,请查看是哪部分	Specifies whether the Owner, Operator, or Agent in Charge address information is identical to previously entered information. If you choose one of these and decide the information is not what you wanted, you may clear and enter the correct information manually.  明确所有者、经营者或负责代理人的地址信息是否与之前输入的信息相同。 如果您选了其中之一,然后确定信息不是您想要的,您可以手动清除并输入正确的信息。 Choose Section 2 if the owner, operator, or agent in charge address information is the same as the facility address information entered in Section 2: Facility Name / Address Information.  - or — Choose Section 3 if the owner, operator, or agent in charge address information is the same as the preferred mailing address information entered in Section 3: Preferred Mailing Address Information.  - or — Choose Section 4 if the owner, operator, or agent in charge address information is the same as the Parent Company address information entered in Section 4: Parent Company Name / Address Information.  - or — Choose Section 7 if the owner, operator, or agent in charge address information is the same as the U. S. Agent address information entered in Section 7: United States Agent.  - or — Choose Clear if you need to clear Section 12 如果所有者、经营者或负责代理人的地址信息与"第2部分: 企业名称/地址信息"中输入的地址信息相同,请选择第2部分。 - 或-如果所有者、经营者或负责代理人的地址信息与"第3部分: 首选邮寄地址信息"中输入的首选邮寄地址信息相同,请选择第3部分。

Field 内容	Description 说明
	- 或- 如果所有者、经营者或负责代理人的地址信息与"第4部分:总公司名称/地址信息"中输入的总公司地址信息相同,请选择第4部分。 - 或- 如果所有者、经营者或负责代理人的地址信息与"第7部分:美国代理商"中输入的 美国代理商的地址信息相同,则选择第7部分。 - 或- 如果您需要清除第十二部分内容,请选择"Clear"键清除。
Street Address Line 1 街道地址第1行	The address of the owner, operator, or agent in charge of the facility being registered. This can be a physical/geographical location or other mailing address. 注册企业所有者、经营者或负责代理人的地址,可以是物理/地理位置或其他邮寄地址。
Street Address Line 2 街道地址第2行	The second address line of the owner, operator, or agent in charge of the facility being registered. You may choose to enter a Suite or Apartment Number.  注册企业所有者、经营者或负责代理人详细地址的第2行。您可以输入房间号。
City 城市	The city in which the owner, operator, or agent in charge of the facility being registered is located. 注册企业所有者、经营者或负责代理人所在城市。
Country/Area 国家/地区	The country/area in which the owner, operator, or agent in charge of the facility being registered is located. 注册企业所有者、经营者或负责代理人所在的国家/地区。
State/Province/Territo ry 州/省/区	The state, province, or territory in which the owner, operator, or agent in charge of the facility being registered is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."  注册企业所有者、经营者或负责代理人所在州、省、或地区。如果适用,从下拉菜单中选择州、省或地区,或者选择"不适用(Not applicable)"。
Zip Code (Postal Code) 邮政编码	The zip code (for domestic addresses) or postal code (for foreign addresses) for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的国内地址或国外地址的邮政编码。
Phone Number: Country Code 电话: 国家区号	For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered. 对于美国境外地址,注册企业所有者、经营者或负责代理人电话号码的三位数字国家区号。
Phone Number: Area/City Code 电话:地区/城市代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人电话号码的三位数字区号(美国国内地址)或城市代码(美国境外地址)。

Field 内容	Description 说明
Phone Number: Phone Number 电话号码	The telephone number for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的电话号码。
Phone Number: Extension 电话号码:分机号	The telephone extension, if any, dialed after the telephone number, for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的电话号码后加拨的分机号(如有)。
FAX Number: Country Code 传真号码: 国家区号	For foreign addresses, the three-digit country code for the telephone number of the FAX machine of the owner, operator, or agent in charge of the facility being registered. 对于美国境外地址,注册企业所有者、经营者或负责代理人传真号码的三位数字国家区号。
FAX Number: Area/City Code 传真号码:地区/城市代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the telephone number of the FAX machine of the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的传真号码的三位数字区号(美国国内地址)或城市代码(美国境外地址)。
FAX Number: FAX Number 传真号码	The telephone number of the FAX machine for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的传真号码。
E-mail Address 电子邮箱地址	An electronic mail address for the owner, operator, or agent in charge of the facility being registered. 注册企业所有者、经营者或负责代理人的电子邮箱地址。

#### **Section 11 – Inspection Statement**

#### 第 11 部分 - 检查声明

Acknowledge that the FDA will be permitted to inspect the facility in the manner permitted by the Federal Food, Drug and Cosmetics Act.

确认已知晓: FDA 可以依据《联邦食品、药品和化妆品法》的规定,以合适的方式对企业进行检查。

#### Section 12 - Certification Statement

#### 第12部分-保证声明

After making other changes to the registration, you may update information about yourself as the submitter of this registration or the person who authorized submission of this registration and certify its truth and accuracy. Once you have completed this section, you will be given the opportunity to review your registration and make any changes before submitting it for processing.

在对注册信息进行更改后,您还可以更新您自己作为注册提交者或授权注册提交者的信息,并保证所提交信息是真实和准确的。完成这部分后您将可以浏览您所填写的注册信息,如果需要,可以在提交前进行修改。

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, the owner, operator, or agent in charge or the individual authorized by the owner, operator, or agent in charge, certifies that the information submitted is true and accurate and that the facility has authorized the submitter to register on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

此表须由企业的所有者、经营者或负责代理人,或者他们授权的个人提交。通过向 FDA 提交此表,企业的所有者、经营者或负责代理人,或者他们授权的个人保证所提交的信息 是真实准确的,且企业已授权注册提交者代表企业提交信息。根据法规 18 U.S.C. 1001 条规定,任何向美国政府作出重大虚假、虚构或欺诈性陈述的人都将受到刑事处罚。

Field 内容	Description 说明
Name of the Submitter 提交者姓名	The first name and last name (surname) of the person submitting this form. 此表提交人的姓名。
Check One Box 勾选一项	Specify whether the owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, is submitting this form. Choose: 说明提交此表的是企业的所有者、经营者或负责代理人,还是所有者、经营者或负责代理人授权的个人。选择:  A. Owner, Operator, or Agent in Charge (Stop here, form is completed) - or - 企业的所有者、经营者或负责代理人(选择选项 A 的话到此处表格填写完成) - 或 - B. Individual Authorized to Submit the Registration (Fill in address below) 被授权提交此注册的个人(在下面填写地址)

Field 内容	Description 说明
Indicate who authorized you to submit the registration 说明谁授权您提交此注册	If you checked box B above (Individual Authorized to Submit the Registration) because you are not the owner, operator, or agent in charge, you need to indicate the person who authorized you to submit this registration. Choose: 如果您勾选了上面的 B 选项(被授权提交注册的个人),因为您不是所有者、经营者或负责代理人,您需要填写授权您提交此注册的人。请选择: Owner, Operator, or Agent in Charge (Stop here, form is completed) - or - 所有者、经营者或负责代理人(选择该选项的话到此处表格填写完成) - 或 - Fill in the name of individual who authorized registration on behalf of owner, operator, or agent in charge. (Fill in address below). 填写代表所有者、经营者或负责代理人授权注册的个人的姓名(在下面填写地址)。
Individual's Name 个人姓名	Fill in the name of individual who authorized registration on behalf of owner, operator, or agent in charge 代表所有者、经营者或负责代理人授权注册的个人姓名
Street Address, Line 1 街道地址第1行	The address of the person who authorized you to submit this form, if applicable. This can be a physical/geographical location or other mailing address. 授权您提交此表的个人的地址(如适用)。该地址可以是物理/地理位置或其他邮寄地址。
Street Address, Line 2 街道地址第2行	The second street name and address number, if applicable. May also enter information such as Suite number.  第二个街道名称和地址号码(如适用)。还可以填写房间号。
City 城市	The city in which the authorizing individual is located. 授权人所在城市。
State/Province/Territory 州/省/区	The state, province, or territory where the authorizing individual is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."  授权人所在州、省、或地区。从下拉菜单中选择州、省或地区(如适用),或选择"不适用(Not applicable)"。
Zip/Postal Code 邮政编码	The zip code (for domestic registrations) or postal code (for foreign registrations) where the authorizing individual is located. 授权人所在地的邮政编码。
Country/Area 国家/地区	The country/area where the authorizing individual is located. 授权人所在国家/地区。
Phone Number: Country Code 电话号码: 国家区号	For foreign addresses, the three-digit country code of the telephone number for the authorizing individual. 如果是美国境 外地址,请填写授权人电话号码的三位数字国家区号。
Phone Number: Area/City Code	The three-digit area code (for domestic addresses) or city code (foreign addresses) of the telephone number for the authorizing individual.

Field 内容	Description 说明
电话号码: 地区/城市区号	授权人电话号码的三位数字区号(美国国内地址)或城市代码(美国境外地址)。
Phone Number: Phone Number 电话号码	The telephone number for the authorizing individual. 授权人的电话号码。
Phone Number: Extension 电话号码: 分机号	The telephone extension, if any, dialed after the telephone number, for the authorizing individual. 授权人的电话号码后加拨的分机号(如有)。
FAX Number: Country Code 传真号码: 国家区号	For foreign addresses, the three-digit country code for the telephone number of the FAX machine of the authorizing individual. 对于美国境外地址,授权人传真号码的三位数字国家区号。
FAX Number: Area/City Code 传真号码:地区/城市代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the FAX machine of the authorizing individual. 授权人传真号码的三位数字区号(美国国内地址)或城市代码(美国境外地址)。
FAX Number: FAX Number 传真号码	The telephone number of the FAX machine of the authorizing individual. 授权人的传真号码。
E-mail Address 电子邮箱地址	The electronic mail address of the authorizing individual. 授权人的电子邮箱地址。

# **Step 5 – Review the Updated Registration**

# 第5步-所更新注册信息的检查

If all the information is updated, select Submit. You may also select "Cancel" to leave the "Update Registration" process but note that any changes made will be lost. The system displays that your registration was successfully updated.

如果所有信息已更新,选择"提交"。您也可以选择"取消(Cancel)"选项离开"更新注册"程序,但是这种操作会丢失之前所做的所有更改。系统显示您的注册已经成功更新。

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