## Food Facility Registration User Guide: Step-by-Step Instructions 食品企业注册用户指南:分步骤说明

#### Online Registration of Food Facilities 食品企业的网上注册

 $\frac{https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities}{food-facilities}$ 

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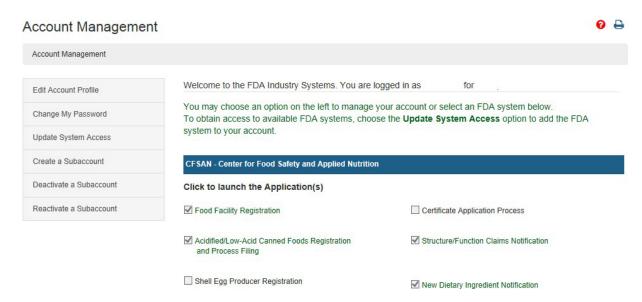
## Register a Food Facility

## 注册一家食品企业

After you have logged in to FDA Industry Systems (FIS), choose "Food Facility Registration" from the list of available systems on the FDA Unified Registration and Listing System (FURLS) Account Management Home Page (Figure 1)

用户在注册登陆美国食品药品管理局(FDA)的行业系统(FIS)后,如Figure 1所示,在美国食品药品管理局FURLS系统账户管理主页上,选择"食品企业注册(Food Facility Registration)"的选项。

#### Figure 1

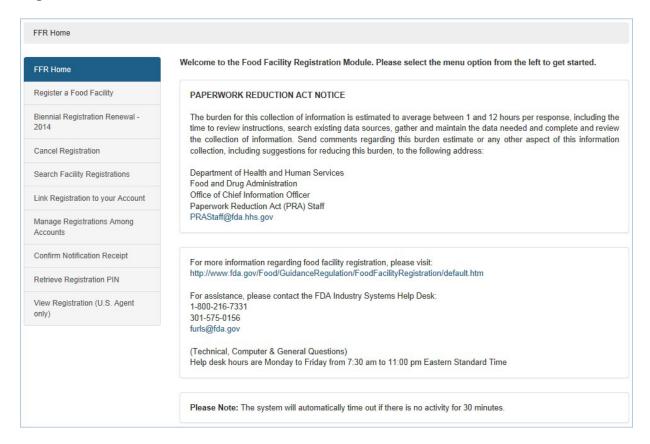


Once in the Food Facility Registration (FFR) system, choose the "Register a Food Facility" main menu option to register a food facility (Figure 2). From the FFR main menu you may also complete a draft registration, update a facility registration, cancel a facility registration, search for one of your facility registrations, manage registrations among your accounts, link registrations to your accounts, confirm receipt of a mailed notification, retrieve your registration's unique PIN if it is ever lost or forgotten, and renew your registration(s) during biennial renewal periods every two years.

进入食品企业注册系统后,如Figure 2所示选择"注册一家食品企业(Register a Food Facility)"。从Figure 2所示的主菜单,你也可以完成初始注册,更新现有注册,取消企业注册,链接注册信息到此账户,搜索注册信息,管理账户的注册,确

认收到信件通知,找回丢失或遗忘的PIN码,并可在两年更新期内进行两年一次的延续注册更新。

#### Figure 2



At the top of every page a status bar will track your progress through each step of the online application process (Figure 3). The help link (i.e., the red question mark at the top of every page) will provide page specific help if needed. For an overview of all the help files available see the FDA Industry Systems Index of Help Pages. At the top right of each page, the "FURLS Home" link will take you back to the FIS/FURLS home page (Figure 1) and the "FFR Home" link will take you to the Food Facility Registration main menu (Figure 2). Choose FURLS Home to log out of your account.

如图3所示,在每一页的顶部有一个状态栏来显示你在网络申请过程的每个步骤的状态。帮助按钮(在每一页右上方的红色问号标志)可以提供该页的帮助信息。如果需要所有的帮助文件,可以在FDA行业系统(FIS)的帮助索引页面找到。在每一页的右上角,点击"FURLS首页(FURLS Home)"链接可以回到FIS/FURLS首页(Figure 1),点击"FFR"首页(FFR Home)可以回到食品企业注册主菜单(Figure 2)。点击"FURLS首页(FURLS Home)"退出账户登陆。

#### Figure 3



Each screen also includes navigation buttons such as the following (Figure 4):

每一页也包含浏览按钮如Figure 4:

#### Figure 4



- Previous go back one screen and continue entering registration information. Information entered on the current screen will not be saved.
- 上一页- 返回上一页输入注册信息。在当前页面输入的信息将不会保存。
- Next go to the next screen and continue entering registration information.
- 下一页- 继续下一页输入注册信息。
- Save and Exit save a partially complete registration. (See Save and Exit-Save a Partially Completed Registration for more details)
- 保存并退出-保存已填写了部分的注册。(详情参见"保存并退出-保存部分完成的注册表)

#### Broker Identification 经销商确认

This section is required. If you are creating a registration for the first time, the following questions will be displayed before Section 1 of the registration process. These questions will identify whether you need to register your facility.

该部分是必填部分。如果你是第一次创建注册,系统会在注册第一部分开始前显示以下问题。以下问题会识别你的企业是否需要注册。

#### Figure 4b

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?  O Yes  No
Are you a broker, distributor, importer/filer?
● Yes ○ No
Do you take physical possession of the food?
○ Yes   No
In accordance with Section 415 of the Federal Food, Drug, and Cosmetic Act, you are not required to register. As defined in 21 CFR 1.225, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register with the FDA. Please be advised that if you choose to proceed with registering, you must comply with all registration requirements and other statutory requirements of the FD&C Act that may apply.

Regardless of the answers chosen, you may continue to register your food facility. You may also view your responses on the registration review page.

无论以上问题你选择的答案是什么,你都可以继续你食品企业的注册。你也可以在注册核对页面上看到你对以上问题的答复。

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

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?	Select "No" if you are not a manufacturer, processer, or packer of food for human or animal consumption in the United States or you do not hold such products.
该企业是否从事食品的生产/加工、包装或储存,这 些食品是供给在美国的人或动物食用的。	如果你并不是供给在美国的人或动物食用的食品的生厂商、加工商、包装商并不储存这些产品,请选择"不是(No)"。
Are you a broker, distributor, importer/filer? 你是否是经销商、分销商、进口商/申报人?	Select "Yes" if you are a broker, distributor, importer/filer. 如果你是经销商、分销商、进口商/申报人,请选择"是(Yes)"。
Do you take physical possession of the goods?你是否实际储存这些货物?	Select "No" if you do not take physical possession of the goods. 如果你不是实际储存这些货物,请选择"不是(No)"。

## **Section 1 - Type of Registration**

## 第一部分- 注册类型

This section is required.

该部分是必填部分。

Indicate the location of the facility being registered and whether you are submitting a registration as a new owner of a previously registered facility (Figure 5). (Subaccounts have the option of determining if their account will be automatically linked to this registration or not). Continue with the registration when complete.

填写注册工厂所在地(Facility Location),你是否作为之前已注册企业的新所有者提交注册申请(Figure 5)。(子账户可以选择他们的账户是否自动链接到该注册)填写完成后继续注册。

#### Figure 5

#### Section 1: Type of Registration

Facility Location	
Please Select	<b>~</b>
Are you the new owner of a previously registered facility?  Yes No	•
If "Yes", provide the following information, if known.	
Previous Owner's Title (Optional)	
Please Select	~
Previous Owner's Name (Optional)	
Previous Owner's Registration Number (Optional)	

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

Facility Location 工厂地址	Specifies whether the facility is located within or outside the United States of America. Choose one of the following two options: Domestic Registration - to indicate that the facility is located in a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico or - Foreign Registration - to indicate a facility is not a domestic facility.  明确工厂位于美国国内还是国外。从以下两个选项中选择:国内注册-明确该工厂位于美国的某个州或美国领土内,哥伦比亚特区,或波多黎各联邦。-或是-海外注册-明确该工厂不是美国国内工厂。
Are You The New Owner Of A Previously Registered Facility? 你是否是已注册 企业的新所有者	Select Yes if you are submitting a registration as a new owner of a previously registered facility. Select No if you are submitting a registration for a facility never previously registered.  如果你是作为新的所有者来提交之前注册过的企业申请,请选择"是"。如果你正在提交从来没有注册过的企业的注册申请,请选择"否"。
Previous owner's title (optional) 原所有者的称呼 (可选)	Select a title for the previous owner from one of the options shown (Mr., Mrs., Miss, Ms, Dr., Other). If "other" is chosen, the system will allow you to enter your own title.  请为原所有者从以下选择一个称呼(先生、夫人、小姐、女士、博士、其他)。如果选择"其他",系统会让你输入合适的称呼。
Previous owner's name (optional) 原所有者姓名 (可选)	If you are a new owner of a previously registered facility, provide the name of the previous owner of the facility, if known. 如果你是一个之前注册过的企业的新的所有者,请提供原所有者姓名(如知晓)。
Previous owner's registration number (optional) 原所有者注册号 (可选)	The Registration Number is assigned to a facility by FDA. If you are a new owner of a previously registered facility, provide the previous owner's registration number for this facility, if known. If the new owner provides the old registration number, FDA will send a notification to the former owner seeking confirmation, and will cancel the former registration upon receipt of confirmation, or FDA's independent confirmation of a change in ownership, whichever occurs first. If the new owner does not provide the old registration number, FDA will keep the old registration in its database until it independently affirms that the facility is under new ownership.
	FDA对每个注册企业都会分配一个注册号码。如果你是之前注册过的企业的新所有者,请提供之前所有者的注册号(如知晓)。如果新所有者提供了原注册号,FDA会给原所有者发送告知并要求原所有者确认,通过原所有者确认后,FDA会注销原注册,或者由FDA确认所有者的变更,哪个先发生就优先依据哪种确认。

	如果新所有者无法提供原注册号码,FDA将在其系统中保留原注册直至FDA确认该企业所有者的变更。
Do you want to link this	If the account is a Subaccounts, then the user have the option of determining if their account will be automatically linked to this registration or not
registration to your enterprise account?	如果该账户是子账户,那么用户可以选择是否自动链接账户到该注册。
你是否想要把该 注册链接到你的 企业账户	

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

## 第二部分-企业名称/地址信息

Enter the name and address of the facility being registered. As an option, you may also enter information about a Preferred Mailing Address if that address is different from the Facility Address.

输入要注册企业工厂名称和地址。如果邮寄地址不同于企业地址,你可以选择输入 首选邮寄地址。

This section is required.

该部分必填。

Enter the name, address, phone number, FAX number, and e-mail address of the facility being registered (Figure 6a).

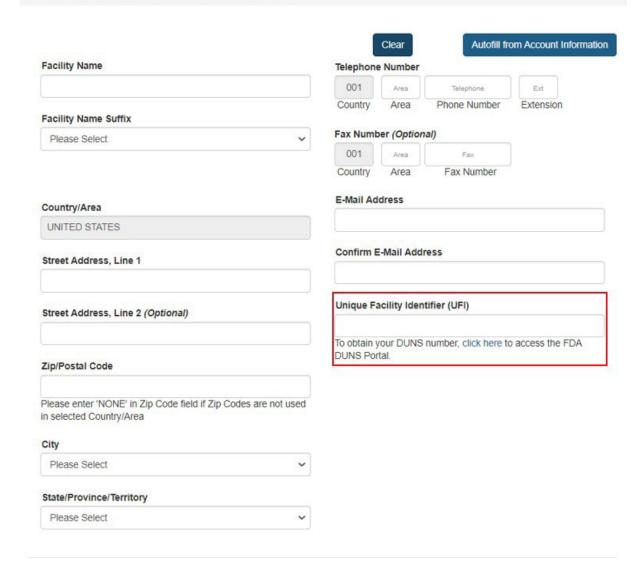
输入注册企业工厂的名称、地址、电话号码、传真号码和需要注册的企业工厂的邮箱地址。(见Figure 6a)

If you would like to have the system fill in this section using the information you entered when you created your Online Account Administration (OAA) account, select the "Autofill from Account Information" option. Select "Clear" to clear all information entered on the screen.

如果你希望使用在创建你的线上管理账户(Online Account Administration)时填写的信息,你可以选择"Autofill from Account Information"选项。选择"Clear"来清除所有输入的信息。

#### Figure 6a

#### **^**Section 2: Facility Name/Address Information



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

Facility Name	The name of the facility being registered.
企业工厂名称	需要注册的企业工厂名称
Facility Name Suffix	The type of company, for example, "company," "corporation," or "limited."
企业名称后缀	企业类型,例如"公司","集团"或"有限公司"。
Country/Area 国家/地区	The country/area in which the facility is located. For foreign registrations, select a country/area from the pull-down menu. (For domestic registrations, United States is filled in automatically.)  工厂所在国家/地区。海外企业注册请从下拉菜单中选择国家/地区。(对
	于美国国内企业的注册,系统会自动填选美国。)
Street Address, Line 1	The street name and address number
工厂地址第一行	工厂所在街道名称和号码
Street Address, Line 2 工厂地址第二行	The second street name and address number, if applicable. May also enter information such as Suite number.
	第二行街道名称和号码(若第一行未写完)。还可以具体输入其他信息 例如门牌号码。
Zip/Postal Code 邮政编码	The Zip/Postal code of selected Country/Area in which the facility is located. Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area.  工厂所在国家/地区的邮政编码。如果所在国家/地区没有邮政编码请输入"NONE"。
City 城市	The city in which the facility is located. 工厂所在城市。
State/Province/Territory 州/省/领地	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."
	工厂所在州/省/领地。从下拉菜单选择工厂所在州、省或者领地,如果不适用请选择"Not applicable"。
Telephone Number Country	For foreign registrations, the three-digit country code of the telephone number for the facility being registered.
电话国家区号	海外注册企业输入工厂所在国家的电话区号(三位数字:例如中国为 <b>086</b> )
Telephone Area Code 电话地区代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the facility being registered. 美国国内企业请填写三位数字的地区代码,海外企业请填写注册工厂所在地的城市电话代码。

Telephone Number Phone Number 注册企业电话	The telephone number of the facility being registered. 注册企业工厂所在地电话。	
Telephone Number Extension	The telephone extension, if any, dialed after the telephone number, of the facility being registered	
电话号码:分机号	注册企业工厂电话如果有分机号,请填写分机号。	
FAX Number(Optional) Country	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the facility being registered.	
传真号: 国家区号(可 选)	海外注册企业工厂所在地的传真机拨号号码的国家区号(三位数字)。	
FAX Number(Optional) Area 传真号码:地区号码(可 选)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the FAX machine of the facility being registered.  美国国内注册企业请填写传真机拨号号码的三位数字地区号码,海外注	
	册企业请填写工厂所在地传真机拨号号码的城市代码。	
FAX Number (Optional) FAX Number	The telephone number of the FAX machine of the facility being registered.	
传真号码 (可选)	注册企业工厂所在地的传真机拨号号码。	
E-mail Address	An electronic mail address for the facility being registered.	
邮箱地址	注册企业工厂的电子邮件地址。	
UFI 企业唯一标识号码	A Unique Facility Identifier (UFI) that allows users to identify the user's facility through a unique number such as a DUNS number.	
	企业的唯一标识号码(UFI):用来识别用户企业的唯一码,例如 DUNS号码(邓白氏编码)。	

## **Section 3 - Preferred Mailing Address Information (Optional)**

## 第三部分-首选邮寄地址信息(可选)

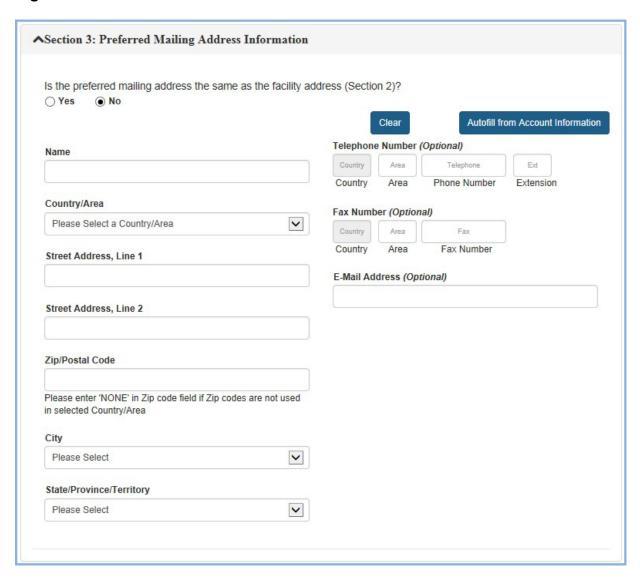
This section is optional but if your facility has a preferred mailing address then enter the information in Section 3 (Figure 6b).

该部分是可选项,如果您企业有不同于工厂地址的首选邮寄地址,请在第三部分输入该信息。详见Figure 6b

Name 名称	The name of the facility being registered. 注册企业工厂名称
Country/Area 国家/地区	The country/area in which the facility is located. For foreign registrations, select a country/area from the pull-down menu. (For domestic registrations, United States is filled in automatically.) 工厂所在国家/地区。海外注册企业请从下拉菜单选择国家/地区。(对于美国国内企业,系统会自动填写)
Street Address, Line 1	The street name and address number
街道地址,第一行	工厂所在街道名称和号码
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.
	第二行街道名称和号码(若第一行未写完)。还可以具体输入其他信息例如门牌号码。
Zip/Postal Code 邮政编码	The Zip/Postal code of selected Country/Area in which the facility is located. Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area.
	工厂所在国家/地区的邮政编码。如果所在国家/地区没有邮政编码请输入"NONE"。
City 城市	The city in which the facility is located.
	工厂所在城市。
State/Province/Territory 州/省/领地	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."
	工厂所在州/省/领地。从下拉菜单选择工厂所在州、省或者领地,如果不适用请选择 "Not applicable"。
Telephone Number (Optional)	For foreign registrations, the three-digit country code of the telephone number for the facility being registered.
Country 电话国家区号(可选)	海外注册企业输入工厂所在国家的电话区号(三位数字:例如中国为 086)

Telephone Number Area (Optional) 电话地区代码 (可 选)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the facility being registered. 美国国内企业请填写三位数字的地区代码,海外企业请填写注册工厂所在地的城市电话代码。
Telephone Number Phone Number (Optional) 注册企业电话 (可选)	The telephone number of the facility being registered. 注册企业工厂所在地电话。
Telephone Number Extension (Optional) 电话号码:分机号(可选)	The telephone extension, if any, dialed after the telephone number, of the facility being registered 注册企业工厂电话如果有分机号,请填写分机号。
FAX Number (Optional) Country 传真号:国家区号(可 选)	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the facility being registered 海外注册企业工厂所在地的传真机拨号号码的国家区号(三位数字)。
FAX Number (Optional) Area 传真号码(可选)	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the FAX machine of the facility being registered.  美国国内注册企业请填写传真机拨号号码的三位数字地区号码,海外注册企业请填写工厂所在地传真机拨号号码的城市代码。
FAX Number (Optional) FAX Number	The telephone number of the FAX machine of the facility being registered.
E-mail Address 邮箱地址	An electronic mail address for the facility being registered. 注册企业工厂的电子邮件地址。

#### Figure 6b



# Section 4 - Parent Company Name/Address Information 第四部分-总公司名称/地址信息

This section is optional; enter if applicable and if different than information entered in Sections 2 or 3.

该部分是可选部分,如果对企业适用或信息不同于第二部分和第三部分已输入信息,请在此部分输入。

The company that owns the facility being registered is referred to as the Parent Company. (Figure 6c);

注册企业的所有者公司是总公司,详见Figure 6c。

The Facility Address and the Parent Company Address do not need to be in the same country/area.

注册企业工厂地址和总公司的地址不需要在同一国家/地区。

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

If information is the same as another section, check which section applies.

如果输入信息与其他已填 写部分的信息相同,请选 择相应的部分 Specifies whether the parent company name/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 choose Clear to undo and fill in the correct information manually.

确认总公司名称/地址信息是否与之前输入的信息相同。如果您选择以下某一选项,并确定默认填入的信息不是您想输入的信息,您可以选择"Clear"来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. or –
- 如果您总公司名称/地址与您在第二部分"企业名称/地址信息" 输入一致,请选择第二部分,或
- 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. or-
- 如果您总公司名称/地址与您在第三部分"首选邮寄地址信息"中输入的信息一致,则选择第三部分,或
- Choose None of the Above if your Parent Company name address is different from the Facility and the Preferred Mailing

	Addresses
	<ul> <li>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"</li> <li>Choose Clear if you need to clear Section 4</li> <li>若清除第四部分已输入内容,请选择"Clear"</li> </ul>
AutoFill from Account Information 从账户自动导入信息	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 company that owns the facility being registered, if different from facility name.  若注册企业工厂和其所有者公司的名称不一致,请填写所有者公司的名称。
Name Suffix 名称后缀	The type of company, for example "company," "corporation," or "Limited." 公司的类型,例如"公司"、"集团公司"、"有限公司"
Country/Area 国家/地区	The country/area in which the parent company is located. For foreign registrations, select a country/area from the pull-down menu. (For domestic registrations, United States is filled in automatically.) 总公司所在国家/地区。对于海外注册企业,请从下拉菜单选择所属国家/地区。(对于美国国内注册企业,系统自动默认填入美国)
Street Address, Line 1 街道地址,第一行	The street name and address number. 工厂所在街道名称和号码
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.  第二行街道名称和号码(若第一行未写完)。还可以具体输入其他信息例如门牌号码。

Zip/Postal Code 邮政编码	The Zip/Postal code of selected Country/Area in which the parent company is located. Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area.  总公司所在国家/地区的邮政编码。如果所在国家/地区没有邮政编码
	请输入 "NONE"。
City	The city in which the parent company is located.
城市	总公司所在城市。
State/Province/Territory 州/省/领地	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/领地。从下拉菜单选择总公司所在州、省或者领地,如果不适用请选择"Not applicable"。
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(可选)	海外注册企业输入总公司所在国家的电话区号(三位数字:例如中国为086)
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(可选)	美国国内企业请填写三位数字的地区代码,海外企业请填写总公司所在地的城市电话代码。
Telephone Number Phone Number (Optional) 电话号码(可选)	The telephone number of the parent company. 总公司所在地电话。
Telephone Number Extension (Optional) 电话号码:分机号	The telephone extension, if any, dialed after the telephone number, of the parent company. 总公司电话如果有分机号,请填写分机号。
FAX Number (Optional) Country	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the parent company.
传真号码国际区号(可 选)	海外注册企业总公司所在地的传真机拨号号码的国家区号(三位数字)。

FAX Number Area (Optional) 传真机地区代码 (可选)	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.  美国国内注册企业请填写总公司传真机拨号号码的三位数字地区号码,海外注册企业请填写总公司所在地传真机拨号号码的城市代码。
FAX Number (Optional) FAX Number 传真号码(可选)	The telephone number of the FAX machine of the parent company. 总公司传真机号码。
E-mail Address (Optional) 邮箱地址(可选)	An electronic mail address for the parent company. 总公司的电子邮件地址。

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

如果企业使用不同于第二部分"企业名称/地址"中填写的企业名称来经营业务,请 在此部分注明其他在贸易过程中使用的名称。例如,可以填写"也使用...来经 营",或"该企业也被称作..."。

#### Figure 6c

is the parent company address the same as the facility ad	dress or prefe	rred maili	ng address (Section	ons 2 and 3)?
Same as Facility Address (Section 2)				
Same as Preferred Mailing Address (Section 3)				
None of the above				
		Clear	Autofill fr	om Account Informatio
Company Name	Telephone	Number		
Company Name	Country	Area	Telephone	Ext
	Country	Area	Phone Number	Extension
Company Name Suffix	Fax Numb	er (Ontion	nal)	
Manufacturing	Country	Area	Fax	
	Country	Area	Fax Number	
	E Mail Ad	dress (Opi	tional)	
Country/Area	L-Mail Au	uress (Op	uonay	
Please Select a Country/Area				
er i resperimentar es				
Street Address, Line 1				
Street Address, Line 2				
Zip/Postal Code				
Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area				
City				
Please Select				
State/Province/Territory				

**Note:** After completing the Section 2, Section 3 and Section 4 in the Step 2 (Contact Information), the system performs address validation for the section 2 and section 3 when the user clicks "NEXT" button.

**注意**:完成第二步(联系信息)的第二部分、第三部分、和第四部分后,当用户点击"NEXT(下一步)"后,系统会对第二部分和第三部分输入的地址进行验证。

**Note:** The messages, "Facility Address is invalid" or "The address submitted has been validated with corrections" means that the system was unable to verify the address entered. You are advised to re-check the address entered and if they are incorrect, select "Edit Address" to correct the information. If the changes made by the system are correct select "Accept Validated Address." If you wish to keep your original address as entered, select "Accept Provided Address" and continue with the registration process (Figure 7a).

注意: 若收到"工厂地址无效"或"地址已被更正"的信息,意味着系统无法验证 您输入的地址。建议您重新检查输入的地址,如果地址输入有误,请选择"Edit Address(编辑地址)"来更正信息。若系统更正的地址是正确的,请选择"Accept Validated Address(接受验证地址)"来按照系统验证地址更正地址。如果您希望继续使用您输入的地址,请选择"Accept Provided Address(接受原输入地址)"来继续使用您输入的地址。之后继续注册程序。详见Figure 7a。

#### Address Validation

×

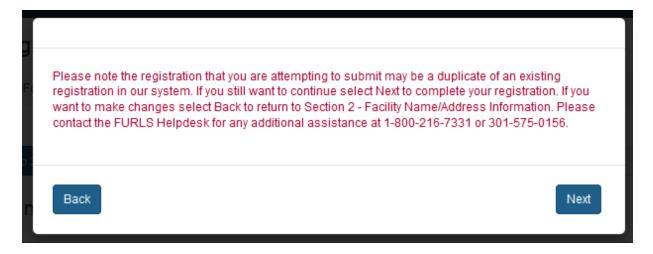
**WARNING**: This address has been verified; however minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made, or correct the address yourself.

YOUR FACILITY VALIDATED FACILITY ADDRESS ADDRESS Street Address, Line 1: Street Address, Line 1: Street Address, Line 2: Street Address, Line 2: City: City: State/Province/Territory: State/Province/Territory: Maryland Maryland Zip/Postal Code: Zip/Postal Code: Country/Area: Country/Area: UNITED STATES UNITED STATES Edit Address Accept Provided Address Accept Validated Address

**Note:** If you receive the following message after your address has been validated, then the system has determined that the new registration that you are attempting to create may be a possible duplicate to an existing registration (Figure 7b). While you may continue to create your new registration, please be aware that it has been flagged and will be reviewed by the FDA.

注意:如果在您确认地址后收到如下信息,意味着系统认为您创建的新注册可能和某个已有注册重复(Figure 7b)。您可以继续创建您的新注册,请注意您此次注册会被标识,FDA会核实。

#### Figure 7b



**Note:** The messages, "Facility Address is invalid" or "The address submitted has been validated with corrections" means that the system was unable to verify the address entered. You are advised to re-check the address entered and if they are incorrect, select "Edit Address" to correct the information. If the changes made by the system are correct select "Accept Validated Address." If you wish to keep your original address as entered, select "Accept Provided Address" and continue with the registration process (Figure 8).

注意: 若收到"工厂地址无效"或"地址已被更正"的信息,意味着系统无法验证 您输入的地址。建议您重新检查输入的地址,如果地址输入有误,请选择"Edit Address(编辑地址)"来更正信息。若系统更正的地址是正确的,请选择"Accept Validated Address(接受验证地址)"。如果您希望继续使用您输入的地址,请选择"Accept Provided Address(接受原输入地址)"来继续使用您输入的地址。之后继续注册程序。详见Figure 8。

#### Address Validation

×

**WARNING**: This address has been verified; however minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made, or correct the address yourself.

YOUR FACILITY VALIDATED FACILITY ADDRESS ADDRESS

Street Address, Line 1: Street Address, Line 1:

Street Address, Line 2: Street Address, Line 2:

City: City:

State/Province/Territory: State/Province/Territory:

Maryland Maryland

Zip/Postal Code: Zip/Postal Code:

Country/Area: Country/Area: UNITED STATES UNITED STATES

Edit Address

Accept Provided Address

Accept Validated Address

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

## 第五部分-企业紧急联系信息

Enter the Facility Emergency Contact Information (Figure 9). 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. If you are registering a foreign facility, the system will prompt you to indicate whether your Emergency Contact information is the same as the U.S. Agent Contact information.

输入企业紧急联系信息(Figure 9)。FDA会用此信息通知企业紧急情况。除非海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。如果您在注册海外企业工厂,系统会自动提示您是否使用美国代理联系信息作为您的紧急联系信息。

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

Title 称谓	The title for the emergency contact, such as "Mr.," or "Mrs." 紧急联系人的称谓,例如"先生",或"女士"。
First Name (Optional) 名字 (可选)	The First name of the emergency contact person. 紧急联系人的名。
Middle Name (Optional) 中间名(可选)	The Middle name of the emergency contact person. 紧急联系人的中间名。
Last Name (Optional) 姓氏(可选)	The Last name of the emergency contact person. 紧急联系人的姓氏。
Job Title (Optional) 职务(可选)	The title for the emergency contact, such as "manager," "ceo," "president." 紧急联系人的职务,例如"经理"、"CEO","总裁"。
Telephone Number Country 电话号码国家区号	Forforeign registrations, the three-digit country code of the telephone number for the facility being registered 海外注册企业输入工厂所在国家的电话区号(三位数字:例如中国为086)

Telephone Number Area	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the facility being registered.
电话地区号码	美国国内企业请填写三位数字的地区代码,海外企业请填写注册工厂所在地的城市电话代码。
Telephone Number Phone	The telephone number of the emergency contact. 紧急联系人电话号码。
Number 电话号码	
Telephone Number	The telephone extension, if any, dialed after the telephone number of the emergency contact.
Extension 电话分机号码	紧急联系人的电话分机号码。
E-mail Address	An electronic mail address for the emergency contact.
邮件地址	紧急联系人的电子邮件地址。

## Figure 9

	Clear	ou choose to designate a	ccount Information
l		Autofill from Ac	ccount Information
ı		Autofill from Ac	ccount Information
		Autofill from Ac	ecount Information
I		Autofill from Ac	ccount Information
Cayman Is	slands, Do	minica, Dominican Republic	c, Grenada,
Vincent ar	nd the Gre		
Telephone	e Number		
Country	Area	Telephone	
Country	Area	Phone Number	
E-Mail Add	dress		
Job Title (	(Optional)		
	Barbuda, Cayman Is Jamaica, Vincent at Caicos IsI Telephone Country Country	Barbuda, Bahamas, Cayman Islands, Do Jamaica, Montserrat Vincent and the Gre Caicos Islands.  Telephone Number  Country  Area	Telephone Number  Country Area Telephone Country Area Phone Number  E-Mail Address

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

## 第六部分-商业贸易中使用的名称

If this facility uses alternate trade names in addition to the name provided in Section 2, you can list them in Section 6: Trade Names (Figure 10).

如果该企业使用除第二部分中列出的企业名称之外,在贸易过程中使用的其他名称,您可以把它列入第六部分:商业贸易中使用的名称。

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

## Alternate Trade Name

If this facility uses alternate trade names in addition to the name provided in Section 2, you can enter the names here

贸易中使用的名称

如果该企业使用除第二部分中列出的企业名称之外,在贸易过程中使用的其他 名称,您可以把该名称输入此处。

#### Figure 10

Section 6: Trade Names
(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))
Are there alternate trade names used by your facility in addition to the name provided in <b>Section 2: Facility Name/Address</b> Information?
Yes O No
Alternate Trade Name #1
Alternate Trade Name #2
Alternate Trade Name #3
Alternate Trade Name #4

### **Section 7 - United States Agent**

## 第七 部分-美国代理

This section is required for the successful registration of foreign facilities.

海外注册企业需要完成此部分。

Enter information about the United States Agent for the facility being registered (Figure 11). Every foreign facility must have a U.S. Agent who acts as the domestic communications representative for that facility (domestic facilities do not require a U.S. Agent). The system will provide address validation upon continuing with the registration.

输入注册企业在美国的代理信息(Figure 11)。每个海外企业都需要有一个美国代理 来作为该企业在美国国内交流的代表(美国国内企业不需要美国代理)。系统会进 行地址验证。

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

**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:美国代理不应与负责代理人混淆。负责代理人无论对于美国国内企业或者海外企业都是另外一种申请。

## 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, 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。

Are you an individual, partnership, corporation, or association?  您是个人、合伙人、公司、还是协会?	Select the option that best describes the U.S. Agent type. 请选择最符合美国代理的选项。
Title (optional)	The title of the U.S. Agent
称谓 (可选)	美国代理的称谓。
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。
Middle Name 中间名	The middle 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中间名。
Last Name 姓氏	The last 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/地区自动填入"United States美国"。
Street Address, Line 1	The street name and address number of the U.S. Agent.
街道地址,第一行	美国代理所在街道名称和号码。
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.
	第二行街道名称和号码(若第一行未写完)。还可以具体输入其他 信息例如门牌号码。
Zip Code	The zip code for the U.S. address of the U.S. Agent.
邮政编码	美国代理地址的邮政编码。
City	The city in which the U.S. Agent is located.
城市	美国代理所在城市。
State/Province/Territory 州/省/领地	The state, province, or territory in which the U.S. Agent is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."
	美国代理所在州/省/领地。从下拉菜单选择所在州、省或者领地,如

	果不适用请选择 "Not applicable"。
Telephone Number Area/City Code 电话号码地区/城市代码	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the U.S. Agent. 美国国内企业请填写三位数字的地区代码,海外企业请填写美国代理所在地的城市电话代码。
Telephone Number Phone Number 电话号码	The telephone number of the U.S. Agent. 美国代理的电话号码。
Telephone Number Extension 电话分机号码	The telephone extension, if any, dialed after the telephone number, of the U.S. Agent. 美国代理电话如果有分机号,请填写分机号
Emergency Contact Telephone Number Country/Area/Phone Number 紧急联系人电话(国家/地区/ 电话号码)	The telephone number of the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency.  如有紧急情况,FDA可以随时联系(一天24小时,一周7天)到的美国代理电话。
Fax Number(optional) Country/Area/Phone Number 传真号码(可选) 国家/地区/电话号码	The FAX number of the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency.  如有紧急情况,FDA可以随时联系(一天24小时,一周7天)到的美国代理传真机电话。
E-mail Address 电子邮件	An electronic mail address for the U.S. Agent. 美国代理的电子邮件地址。

#### Figure 11

#### Section 7: United States Agent Note: If you modify this address, please review the address in Section(s) 11 to verify that those addresses are still correct. (To be completed by facilities located outside any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico) If you are assigning a new US agent please select Yes. If you are simply changing the name or address of your current US agent please select No. (Note: Registration number and PIN will be mailed to your new U.S Agent if you select Yes.) O Yes Clear Autofill from Account Information Are you an individual, partnership, corporation, or association? Please Select ~ Title (Optional) Telephone Number 001 Telephone Ext Country Area Phone Number Extension First Name **Emergency Contact Telephone Number** 001 Middle Name (Optional) Country Phone Number Fax Number (Optional) **Last Name** Country Area Phone Number E-Mail Address Country/Area UNITED STATES Street Address, Line 1 Street Address, Line 2 Zip Code Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area City Please Select ~ State/Province/Territory V Please Select

## **Section 8 - Seasonal Facility Dates of Operation (Optional)**

## 第八部分-季节性企业的运营日期(可选)

Indicate the approximate dates during which this facility operates if it operates on a seasonal basis. You may select up to two different Harvest periods with a start and end month (Figure 12).

如果企业按照季节性运营,请注明企业工厂运营的大致日期。您可以选填两个不同的时段(每个时段包括开始和结束日期)。详见Figure 12。

Dates of Operation For Harvest 1 第一个运营日期	The approximate months during which the facility operates, if it operates on a seasonal basis. Select Start Month and End Month.  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。
Dates of Operation For Harvest 2 第二个运营日期	The approximate months during which the facility operates, if it operates on a seasonal basis. Select Start Month and End Month.  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。

#### Figure 12

#### Section 8: Seasonal Facility Dates of Operation (Optional)

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis (Optional).

# Dates of Operation Harvest 1 Start Month Please Select Please Select Tharvest 2 Start Month End Month End Month Please Select Please Select Please Select Please Select Please Select Please Select

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

## 第九部分-主要产品类别-人类/动物/人和动物

Based on your facility's activities, you may choose Food for Human Consumption and/or Food for Animal Consumption as shown in (Figure 13).

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(如下图 Figure 13)

This section is required.

该部分必填。

#### Figure 13

Section 9: General Product Categories - Human/Animal/Both
☐ Food for Human Consumption
Food for Animal Consumption

# Section 9a – General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility

第9a部分 – 主要产品类别 – 供人类食用的食品品;以及企业的操作类型

This section is required.

本部分内容必填。

All facilities that are registering must complete section 9a, 9b, or both sections if applicable. Select as many of the categories as appropriate.

如果适用,所有注册企业必须完成第9a、9b或两部分。填写时请尽量全面选择产品类别。

If your facility does not manufacture, process, pack or hold food for human consumption, select box 37: "... NONE OF THE ABOVE FOOD CATEGORIES APPLY". You may then enter in your own description in the text box provided.

如果你的企业不生产、加工、包装或储存供人类食用的食品,请勾选37项:"上述食品类别都不适用"。你需要在其后的对话框里输入自己的描述。

The Type of Activity Conducted at the Facility selections is optional. You may check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food. For example, if the Product Category "alcoholic beverages, number 1" is selected, and you perform as a "manufacturer/processor" you would select that option on line 2 in the eighth column.

企业操作类型为选填项。你可以选择企业生产加工、包装或存储食品过程中所进行操作的所有类型。例如,如果选择的产品类型为"1.酒精饮料alcoholic beverages",你的企业为"生产/加工商manufacturer/processor",你则需要选择第八栏第二行的选项。

"Select all" and "Unselect All" options are also available which enables the user to select all the options available and unselect all the options selected at once.

这里设置了"全选"和"全不选"项可以让用户一次性选择或不选择全部选项。

Examples for Section 9a (Figure 14a and Figure 14b).

第9a部分的例子(图14a和图14b)

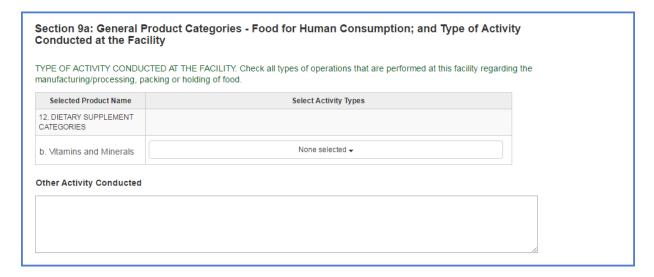
Examples for Section 9b (Figure 15a and Figure 15b).

第9b部分的例子(图15a和图15b)

## Figure 14a

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility				
To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.				
Select All Unselect All				
☐ 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]				
□ 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula				
☑ 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]				
☐ 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]				
☐ 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]				
☐ 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING / INSTANT CEREALS [21 CFR 170.3 (n) (4)]				

# Figure 14b



# Section 9b – General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility

第**9b**部分 – 主要产品类别 – 供动物食用的食品;以及企业的操作类型

Select as many of the 32 categories as appropriate. (See Figure 15a) If none of the mandatory categories apply, select box 33: "... NONE OF THE ABOVE FOOD CATEGORIES APPLY". You may then enter in your own description in the text box provided.

在这32种类别中选择所有适用的选项。(图15)如果没有适合的选项,请勾选33项: "上述食品类别都不适用"。你需要在其后的对话框里输入自己的描述。

"Select all" and "Unselect All" options are also available which enables the user to select all the options available and unselect all the options selected at once.

这里设置了"全选"和"全不选"项可以让用户一次性选择或不选择全部选项。

**Note:** For more information on the use of food product categories in registration of food facilities see Guidance for Industry: Necessity of the Use of Food Product Categories in Registration of Food Facilities. 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:如果需要食品企业注册过程中如何使用食品类别的更多信息,请参见企业指南:在食品企业注册中使用食品类别的必要性。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)。

#### Figure 15a

Section 9b: General Product Categories - Food for Animal Consumption; and Type of Activity Conducted at the Facility

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 33.

Select All Unselect All

1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)

2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)

3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS

4. AMINO ACIDS OR RELATED PRODUCTS

5. ANIMAL PROTEIN PRODUCTS

6. BOTANICALS AND HERBS

#### Figure 15b



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

# 第10部分 - 所有者/经营者/负责代理人信息

This section is required.

本部分内容必填。

If the contact information for the owner, operator, or agent in charge is the same as that in another section of the form, choose the circle corresponding to that section; Otherwise enter the information as requested (Figure 16).

如果所有者、经营者或负责代理人的信息与本表的其他部分相同,点击与之对应部分选项前的圆圈。否则请按要求填写信息(图16)。

Name of Entity or Individual who is the Owner, Operator, or Agent in charge. If information is the same as another section of the form, check which section.

所有者、经营者或负责代 理人的姓名。如果该信息 与本表其他部分相同,请 选择是哪部分。 The name of the person or entity who is the owner, operator, or agent in charge of the facility being registered. 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. 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

注册企业的所有者、经营者或负责代理人的人员姓名或单位名称。所指的所有者、经营者或负责代理人的地址信息是否与先前输入的信息相同。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。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。-或者

- 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 - For foreign facilities, 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 None of the above if you need to enter new information.

	- 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。- 或者 - 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。- 或者 - 对于外国企业,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。- 或者 - 如果您需要输入新信息,请选择以上无。
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
Street Address Line 1 详细地址第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。 这可以是物理/地理位置或其他邮寄地址。
Street Address Line 2 详细地址第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。你可以输入房间号。
Zip /Postal Code 邮编	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。
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
State/Province/Territory 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)"。

Telephone Number Country	For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered.
电话 – 国家号	对于国外地址,注册企业所有者、经营者或负责代理人电话号码的三位 国家号。
Telephone Number Area 电话 – 区号	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区号 (国内)或城市号(国外)。
Telephone Number Phone Number	The telephone number for the owner, operator, or agent in charge of the facility being registered.
电话号码	注册企业所有者、经营者或负责代理人的电话号码。
Telephone Number Extension 电话分机号	The telephone extension, if any, dialed after the telephone number, 如果需要拨打,则填写分机号。
Fax Number(optional) Country 传真 (选填) – 国家号	For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered.  对于国外地址,注册企业所有者、经营者或负责代理人传真号的三位国家号。
Fax Number(optional) Area	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.
传真 (选填) – 区号	注册企业所有者、经营者或负责代理人传真机的电话号码的三位区号 (国内)或城市号(国外)。
Fax Number(optional) Fax Number	The FAX number 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。
传真号 (选填)	在加工亚/用有v 红旨有以贝贝凡连八明的具 5 时。
E-mail Address 电子邮件	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件地址。

# Figure 16

i igaio io				
Section 10: Owner, Operator, or Agent-in-Cha	rge Infor	mation	1	
Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge				
Is their contact information the same as any of the previous section	ons?			
Same as Facility Address (Section 2)				
<ul> <li>Same as Preferred Mailing Address (Section 3)</li> </ul>				
<ul> <li>Same as Parent Mailing Address (Section 4)</li> </ul>				
<ul><li>Same as U.S. Agent Information (Section 7)</li></ul>				
None of the above				
				_
				Clear
Country/Area	Telephone	e Number		
Please Select a Country/Area	Country	Area	Telephone	Ext
Street Address, Line 1	Country	Area	Phone Number	Extension
Short Address, Line 1	Fax Numb	er (Option	nal)	
	Country	Area	Fax	
Street Address, Line 2	Country	Area	Fax Number	
	E-Mail Ad	dress		
Zip/Postal Code				
Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area				
City (Non US)				
State/Province/Territory				
lacksquare				

# **Section 11 – Inspection Statement**

# 第11部分 - 检查声明

This section is required.

本部分内容必填。

Select the check box that you acknowledge the FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug and Cosmetics Act (Figure 17).

选择此框代表您已经同意允许FDA依据联邦食品、药品和化妆品法中规定的时间和 方式对企业进行检查(图17)。

# Figure 17

### Section 11: Inspection Statement

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

# Section 12 – Certification Statement

# 第12部分 - 保证声明

This section is required.

本部分内容必填。

Enter information about yourself as the submitter of this registration, the person who authorized submission of this registration, and certify its truth and accuracy (Figure 18a and Figure 18b). 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.

注册提交者或被授权的注册提交者需要输入自己的信息,证明提交信息是真实与准确的(图18a和图18b)。一旦您完成了这部分,您将可以浏览您所提交的注册信息,并在提交前进行修改。

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.

If option B is selected then a screen will pop up and all the details have to be filled.

企业的所有者,经营者或负责代理人,或者被他们授权的个体必须提交此表。 如果选择B选项,则屏幕会弹出对话框,并需要填写对话框内的详细信息。

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.

向FDA提交此表,即代表企业的所有者,经营者或负责代理人,或者被他们授权的个体证明所提交的信息是真实准确的,并且企业已经授权注册提交者代表自己提交信息。在18 U.S.C. 1001条规定,任何向美国政府作出严重虚假、虚构或欺诈性陈述的人都将受到刑事处罚。

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

Check Box 勾选项	The Secretary will be permitted to inspect facility at the time and in the manner permitted by this act.  美国卫生与公众服务部部长批准根据法典规定的时间和方式对企业进行检查。
Name of the Submitter 提交者姓名	The first name and last name (surname) of the person submitting this form 提交此表的人员姓名
Check one Box Indicate who authorized you to submit the registration	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:
<b>勾选一项,表明谁授权您</b> 提交此注册	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、经营者或负责负责代理人授权的个体。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(结束,表格完成) - 或 -  B. Individual Authorized to Submit the Registration (Fill in address below) - 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 identify the person who authorized you to submit this registration. Choose: Owner, Operator, or Agent in Charge (Stop here, form is completed.) - or - Fill in the name of individual who authorized registration on behalf of owner, operator, or agent in charge (Fill in address below).  被授权提交此注册的个体(填写下面的地址) - 如果因为您不是所有者、经营者或负责代理人,您勾选了上面的B选项(被授权提交注册个人),您需要确定谁授权您提交此注册。请选择:所有者、经营者或负责代理人(结束,表格已完成。) - 或 - 填写被授权代表所有者、经营者或负责代理人进行注册的个人姓名(填写下面的地址如)。
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
	被授权代表所有者、经营者或负责代理人进行注册的个人姓名
Country/Area	The country/area in which the Authorizing Individual is located
国家/地区	被授权人所在国家/地区
Street Address Line 1	The street name and address number of the Authorizing Individual

详细地址第1行	被授权人的地址和街道号
Street Address Line 2 详细地址第2行	The second street name and address number, if applicable. May also enter information such as Suite number.
	如果需要,填写第二行地址和街道号。可能还需要填写房间号。
Zip /Postal Code 邮编	The zip code for the U.S. address of the Authorizing Individual 被授权人在美国地址的邮编。
City	The city in which the Authorizing Individual is located.
城市	被授权人所在城市。
State/Province/Territory 州/省/区	The state, province, or territory in which the Authorizing Individual is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."
	被授权人所在州、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)"。
Telephone Number Country	The Country code (for foreign addresses) of the telephone number for the Authorizing Individual.
电话 – 国家号	被授权人电话号码的国家号(对国外地址对应的电话号码)。
Telephone Number Area	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the Authorizing Individual.
电话 – 区号	被授权人电话号码的三位区号(国内)或城市号(国外)。
Telephone Number Phone Number 电话号码	The telephone number of the Authorizing Individual.被授权人的电话号码。
Telephone Number Extension	The telephone extension, if any, dialed after the telephone number, Authorizing Individual.
电话分机号	如果需要拨打,则填写被授权人的分机号。
Fax Number(optional) Country	The Country code (for foreign addresses) of the FAX machine for the Authorizing Individual. 被授权人传真机号的三位国家号(国外地址)。
传真 (选填) - 国家号	
Fax Number(optional) Area	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number of the FAX machine for the Authorizing Individual.

传真 (选填) - 区号	被授权人传真机的电话号码的三位区号(国内)或城市号(国外)。
Fax Number(optional) Fax Number 传真号 (选填)	The telephone number of the Fax machine of the Authorizing Individual. 被授权人的传真号码。
E-mail Address 电子邮件	The electronic mail address of the authorizing individual. 被授权人的电子邮件地址。

#### Figure 18a

#### **Section 12: Certification Statement**

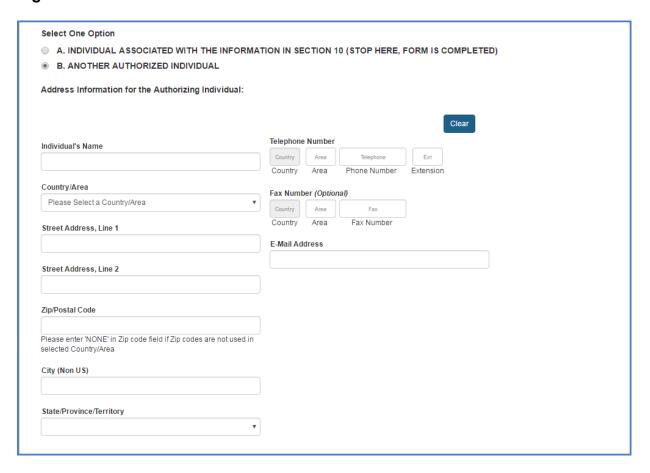
The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. 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.

Name of the	e Submitter		

#### **Select One Option**

- A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
- B. ANOTHER AUTHORIZED INDIVIDUAL

# Figure 18b



# **Registration Review**

# 注册信息检查

Review your registration before submitting it for processing. (Figure 19, partial view) Selecting the EDIT button for a section brings up the corresponding data entry screen from which you can edit and save changes.

在提交前,请检查一下填写的注册信息。(图19,部分显示)选择EDIT选项钮,可以把之前相关的输入信息屏幕调出,你可以编辑和保存修改。

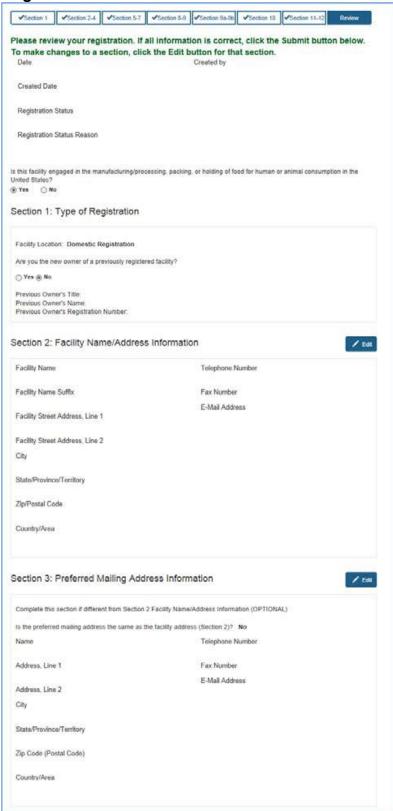
Select Submit to submit the registration or Cancel to cancel the submission.

选择"提交(Submit)"进行注册提交,或选择"取消(Cancel)"取消提交。

**Note:** The Facility Location under Section 1: Type of Registration (in which you indicate whether this is a domestic or foreign facility) cannot be changed at this point. If you wish to change the Facility Location, you must Cancel this registration and begin a new registration.

**注意:**在第一部分中的企业工厂所在地:注册类型(分为所在地是国内或国外)在这里是不能修改的。如果您需要修改工厂所在地,您需要取消此注册,重新进行注册。

## Figure 19



# **Registration Successful**

# 注册成功

A message indicates that your registration was submitted successfully, and your Registration Number and PIN are displayed (Figure 20). Record these numbers for your records.

注册成功后,系统会出现一条信息显示注册提交成功,里面包括注册号和PIN码(图 20).请记下这些号码。

If you plan to have another account owner update this registration, you may give this person the registration number and PIN to gain access. Note, however, that providing this person with the registration number and PIN also allows that person to cancel the registration.

如果您需要使用另一个账号更新注册信息,您可以告知注册号和PIN来进入系统。但是请注意:如果您告知某人您的注册号和PIN码,意味着此人可以注销此注册。

#### **View Complete Registration**

#### 查看全部注册内容

To view the entire registration in its final form, select View Complete Registration. Using the buttons at the bottom of the screen, you can print a copy of the registration for your records. Or, you can return to the FFRM Main Menu to enter another registration or complete other registration tasks.

想看最终版整个注册表格,选择查看完整注册(View Complete Registration)。使用屏幕下方的按钮选项,您可以打印注册记录。或者您可以回到FFRM主菜单(Main Menu)开始进行另一个注册或完成其他注册任务。

**Note:** The registration number and PIN are displayed at the top of the registration form.

注意:注册号和PIN码会显示在注册表的顶端。

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

Registration Number	The number assigned by FDA to this facility's registration		
注册号	FDA赋予企业的注册号码		
PIN	The Personal Identification Number for this facility's registration		
	该注册企业的个人识别号码		
Registration Expiration Date	The date your facility's registration will expire		
注册失效日期	您企业注册失效的日期		

The system displays this message only if it is Domestic Registration Submitted by Owner operator.

只有在企业所有者提交的国内企业注册时,系统才会显示此信息。

### Figure 20

This message pops up for other scenarios.

其他情况,弹出窗口将显示这条信息。

# **Registration Submitted - Verification Pending**

In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. agent. The U.S. agent that you have listed has been contacted and should respond to our confirmation request by 10/16/2016. Upon successful confirmation, the registration number and pin will be issued.

Once received, please keep the registration number and PIN for your records.

# Save and Exit - Save a Partially Completed Registration 保存并退出 - 保存未填写完整的注册信息

Upon completing at least up to Section 2 of the Registration, the system will allow the user to save their registration as a draft. This will allow you to save a partially completed registration and return at a later time to complete the registration.

当完成了注册的第二部分内容,系统将允许用户保存注册信息草稿。这将允许您保存部分完成的注册信息,以便以后回来继续完成注册。

**Please Note** – the registration will be saved up to 7 days after the initial draft was completed. You must complete and submit the registration within 7 days or your draft will be deleted from the system.

**请注意** – 在草稿完成后,注册信息将最多保留7天。您必须在7天内完成并提交注册信息,否则所有信息将被从系统里删除。

When you choose to Save and Exit, the system will advise you that a reference number has been assigned (Figure 21). This is temporary and may be used as a reference to complete your registration.

如果您选择"保存并退出(Save and Exit)",系统将告知您,已分配了一个参考号码(图21).这是临时号码,可以做为完成注册的参考。

#### Figure 21

#### Draft Confirmation 🗸

The food facility registration information you provided has been saved. This information will be available for you to edit and complete for seven days from the date you began your registration. If you do not complete your online registration within that time and submit it in FFRM, this registration information will be removed from FFRM.

You may edit, complete, and submit your online registration by logging in to FURLS and clicking the 'Complete Draft Registration' button located on the FFR Home. When you return to complete this registration, the reference code is 47256.

NOTE: FDA will not issue your food facility registration number until your online registration form has been completed and submitted in FFRM.

To access your draft registrations, select the Complete Draft Registration button from the FFRM main menu. Note: This button will only show up on the FFRM Main Menu if you have saved at least one draft registration using the save and exit option.

为了进入注册草稿,在FFRM主菜单中选择"完成注册草稿(Complete Draft Registration)"按钮选项。注意:只有在您使用保存并退出选项,至少保存了一份注册草稿的情况下,这个按钮选项才会在FFRM主菜单中显示。

After choosing the Complete Draft Registration button the system will display all draft registrations that are available for you to complete (Figure 22).

在选择"完成注册草稿(Complete Draft Registration)"按钮选项后,系统将显示所有您可以完成的注册草稿(图22)。

#### Figure 22

Complete Draft Registration					
Your account has access to the following draft registrations. Please click on a reference code to select a registration for update to complete the draft registration.					
Show 25 v entries					
Reference Line Code	Facility Name	Facility Address	11		
47256					
Showing 1 to 1 of 1 entries					

Select the draft you wish to complete by clicking on the reference number. The system will display the registration with all the information that was previously entered (Figure 23). You may select the "Edit" option next to the section you wish to complete. The system will walk you through the remainder of the registration.

选择您希望编辑完成的草稿,点击参考号码。系统会显示此注册所有之前已经输入的信息(图23).可以选择您希望编辑的草稿旁边的"编辑(Edit)"选项。系统将引导您完成注册余下的部分。

# Figure 23

