Food Facility Registration User Guide: Registration of Food Facilities Step-by-Step Instructions 食品企业设施注册用户指南: 食品企业设施注册分步骤说明

Food Facility Registration User Guide: Step-by-Step Instructions for Registration | FDA

Table of Contents 目录

Register a Food Facility 注册一个食品企业设施	4
Section 1 - Type of Registration	9
第1部分- 注册类型	9
Section 2 - Facility Name / Address Information	13
第2部分-企业名称/地址信息	13
Section 3 - Preferred Mailing Address Information (Optional)	17
第3部分-首选邮寄地址信息(选填项)	17
Section 4 - Parent Company Name/Address Information	20
第4部分-总公司名称/地址信息	20
Section 5 - Facility Emergency Contact Information	27
第5部分-企业紧急联系信息	27
Section 6 - Trade Names	30
第6部分-商业名称	30
Section 7 - United States Agent	31
第7部分-美国代理	31
Section 8 - Seasonal Facility Dates of Operation (Optional)	31
第8部分 - 企业的季节性运营日期(选填项)	31
Section 9 - General Product Categories – Human/Animal/Both	32
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	32
Section 9a – General Product Categories – Food for	32
Human Consumption; and Type of Activity Conducted at the Facility	32
第9a部分 – 一般产品类别 – 供人类食用的食品;以及企业设施的活动类型	32
Section 9b – General Product Categories – Food for	34
Animal Consumption; and Type of Activity Conducted at the Facility	34
第9b部分 – 一般产品类别 – 供动物食用的食品;以及企业的活动类型	34
Section 10 – Owner, Operator, or Agent in Charge Information	36
第10部分 – 所有者、经营者或负责代理人信息	36
Section 11 – Inspection Statement	40
第11部分 – 检查声明	40
Section 12 – Certification Statement	41
第12部分 – 保证声明	41
Registration Review	46
注册信息检查	46

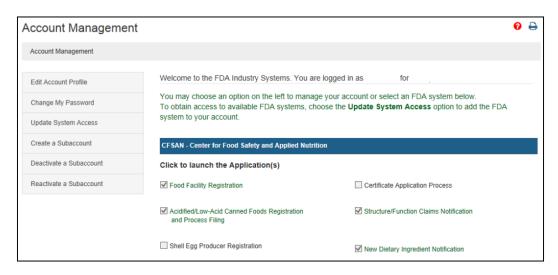
Registration Successful	48
注册成功4	48
View Complete Registration	48
查看完整注册	48
Save and Exit - Save a Partially Completed Registration	51
保存并退出 – 保存已部分完成的注册信息	51

Register a Food Facility 注册一个食品企业设施

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).

用户登陆美国食品药品管理局(FDA)的企业系统(FIS)后,在FDA FURLS系统账户管理主页上,从一系列可用系统中选择"食品企业设施注册(Food Facility Registration)"(图1)。

Figure 1 – FURLS Account Management Home Page 图1 – FURLS 账户管理主页



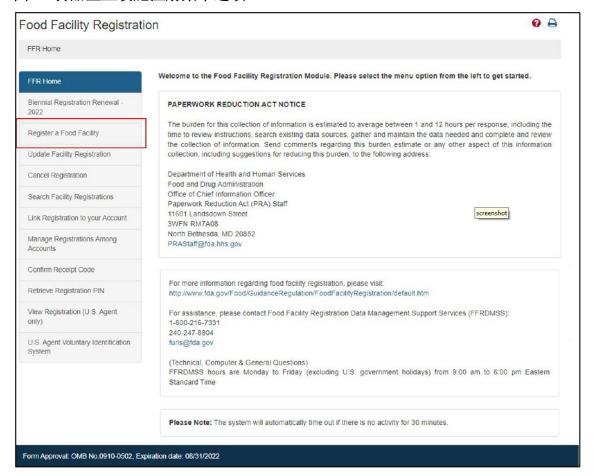
Once in the Food Facility Registration (FFR) system, choose the "Register a Food Facility" main menu option to register a food facility (Figure 2). From the FFR main menu you may also:

- Complete a draft registration
- Update a facility registration
- Cancel a facility registration
- Link a registration(s) to your account
- Search for one of your facility registrations
- Manage registrations among your accounts
- Confirm receipt of a mailed notification
- Retrieve your registration's unique PIN if it is ever lost or forgotten
- Renew your registration(s) during biennial renewal periods every two years

进入食品企业设施注册系统(FFR)后,选择"注册食品企业设施(Register a Food Facility)"主菜单选项来进行食品企业设施注册(图2)。从FFR主菜单,您还可以:

- 完成初始注册
- 更新企业设施注册
- 取消企业设施注册
- 将注册关联到您的账户
- 搜索企业设施注册
- 管理账户的注册
- 确认收到信件通知
- 找回丢失或遗忘的注册密码
- 在每两年延续注册期内进行两年一次的延续注册。

Figure 2 – Register a Food Facility Menu Option 图2 – 食品企业设施注册菜单选项



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您在线上申请过程中完成每个步骤的进程。帮助链接(每一页右上方的红色问号)可以提供该页的帮助信息。所有的帮助文件可以在FDA企业系统(FIS)的帮助页面索引中找到。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(图1),点击"FFR首页(FFR Home)"可以回到食品企业设施注册主菜单(图2)。点击"FURLS首页(FURLS Home)"退出账户登陆。

Figure 3 – Online Application Progress 图3–线上申请进程



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

每一页也包含导航按钮如下(图4):

- **Previous** Go back one screen and continue entering registration information. Information entered on the current screen will not be saved.
- 上一页 返回上一页继续输入注册信息。在当前页面输入的信息将不会被保存。
- Save and Exit Save a partially complete registration. See Save and Exit-Save a
 Partially Completed Registration for details.
- **保存并退出** 保存已填写了部分信息的注册。详情参见"**保存并退出-保存部分完成** 的注册"。
- Next Go to the next screen and continue entering registration information.
- **下一页** 去往下一页继续输入注册信息。

Figure 4 – Navigation Buttons 图4 –导航按钮



Broker Identification 是否是经销商

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 (Figure 5). These questions will identify whether you need to register your facility.

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

Figure 5 – Broker Identification Questions

图 5 - 界定企业是否是经销商的问题

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.

无论以上问题您选择的答案是什么,您都可以继续您食品企业的注册。您也可以在注册核对页面查看您就以上问题所选的答案。

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

Field 内容	Description 说明
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. 如果您并不是供在美国的人或动物食用的食品的生厂商、加
该企业是否从事供在美国的人或动物食	工商、包装商或您并不存储这些产品,请选择"不是(No)
用食品的生产/加工、包装或存储。 ————————————————————————————————————	<i>II</i> •
Are you a broker, distributor, importer/filer?	Select "Yes" if you are a broker, distributor, and importer/filer.
您是否是经销商、分销商、进口商/申报	如果您是经销商、分销商、进口商/申报人,请选择
人?	"是 (Yes) "。
Do you take physical possession of the goods? 您是否实际储存这些货物?	Select "No" if you do not take physical possession of the goods. 如果您不是实际储存这些货物,请选择"不是 (No)"。

Section 1 - Type of Registration 第1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 6). (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,您是否作为之前已注册企业的新所有者提交注册申请(图 6)。(子账户可以选择他们的账户是否自动与该注册关联)。填写完成后继续注册。

Figure 6 – Type of Registration 图6 – 注册类型

Section 1: Type of Registration
Facility Location
Please Select 🗸
Do you want to re-register a facility that has passed the registration renewal deadline?
● Yes ○ No
Please enter the Registration Number of the registration that has passed the registration renewal deadline.
Registration Number
Are you the new owner of a previously registered facility? O Yes O 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

Field 内容	Description 说明
Facility Location	Specifies whether the facility is located within or outside the United States of America. Choose one of the following two options:
	Domestic Registration - Indicates that the facility is located in a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
	• Foreign Registration - Indicates a facility is not a domestic facility.
	明确工厂位于美国境内还是境外。 从以下两个选项中选择:
	国内注册-说明该工厂位于美国的某个州或美国领土境内、哥伦比亚特区,或波多黎各联邦。
	• 国外注册-说明该工厂不是美国国内工厂。
Do you want to re- register a facility that has passed the	Select Yes if you are submitting a registration for a previously registered facility that had passed the registration renewal deadline.
registration renewal	Select No if you are submitting a registration for a facility never previously registered.
deadline? 是否要重新注册已超过延续注册截止	如果您提交的是已超过延续注册截止日期的先前注册设施的注册,请选择"是"。
日期的企业设施?	如果您提交的是以前从未注册过的设施的注册,请选择"否"。
Registration Number	Displayed if you are re-registering a facility that has passed the registration renewal deadline.
注册号	Enter the registration number of the facility you want to re-register.
	如果您要重新注册已超过延续注册截止日期的设施,则会显示需要输入注册号。
	输入要重新注册的设施的注册号。
Are you the new owner of a	Select Yes if you are submitting a registration as a new owner of a previously registered facility.
previously registered facility?	Select No if you are submitting a registration for a facility never previously registered.
您是否是已注册企	如果您是作为之前注册过的企业的新所有者来提交注册申请,请选择"是"。
业的新所有者	如果您正在提交从未注册过的企业的注册申请,请选择"否"。
Previous owner's title (optional)	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.
原所有者的称呼 (选填项)	请为原所有者从所显示选项中选择一个称呼(先生、夫人、小姐、女士、博士、其他)。如果选择"其他",您可以输入自定义的称呼。

Field 内容	Description 说明
Previous owner's name (optional)	If you are a new owner of a previously registered facility, provide the name of the previous owner of the facility, if known.
原所有者姓名(选 填项)	如果您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 (选填项)	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会为每个注册企业分配一个注册号。 如果您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会给原所有者发通知要求原所有者确认, 原所有者确认后,FDA会注销原注册,或者由FDA自行确认所有者的变更,哪个先发生就优先依据哪种确认。如果新所有者不提供原注册号码,FDA将在其系统中保留原注册直至FDA确认该企业已变更了所有者。
Do you want to link this registration to your enterprise account? 您是否想要把该注册关联到您的企业账户	If the account is a Subaccounts, then the user has the option of determining if their account will be automatically linked to this registration or not. 如果该账户是子账户,那么用户可以选择是否自动关联账户到该注册。

Section 2 - Facility Name / Address Information 第2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.

输入要注册企业设施/工厂名称和地址。如果邮寄地址不同于企业工厂地址,您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 7).

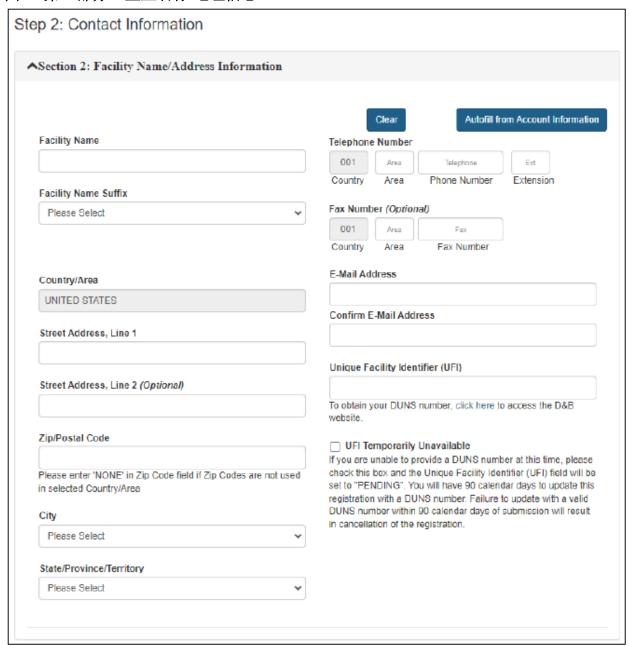
输入注册企业工厂的名称、地址、电话号码、传真号码和电子邮箱。(见图7)

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.

如果您希望系统使用您创建在线账户管理(OAA)账户时输入的信息自动填写此部分内容,请选择"Autofill from Account Information"选项。选择"Clear"来清除页面上所有输入的信息。

Figure 7 – Section 2: Facility Name/Address Information

图7-第二部分:企业名称/地址信息



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

Field 内容	Description 说明
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"company"、"corporation"或"limited"。
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
街道地址第一行	工厂所在街道名称和地址号码
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。
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、省或领地。从下拉菜单选择工厂所在州、省或领地,如果不适用请选择"Not applicable"。
Telephone Number—Country 电话—国家区号	For foreign registrations, the three-digit country code of the telephone number for the facility being registered.
\	海外注册企业输入三位数字的工厂所在国家的电话区号。
Telephone Number—Area 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.
	注册工厂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)。

Field 内容	Description 说明
Telephone Number— Phone Number	The telephone number of the facility being registered. 注册企业工厂的电话号码。
注册企业电话号码	
Telephone Number— Extension	The telephone extension, if any, dialed after the telephone number, of the facility being registered
电话号码一分机号	注册企业工厂电话如果有分机号,请填写分机号。
FAX Number—Country (Optional)	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the facility being registered.
传真号码—国家区号(选填 项)	海外注册企业工厂传真号码的三位数字国家区号。
FAX Number—Area (Optional) 传真号码—地区号码(选填 项)	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. 注册工厂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) 传真号码(选填项)	The telephone number of the FAX machine of the facility being registered. 注册企业工厂的传真号码。
E-mail Address 电子邮箱	An electronic mail address for the facility being registered. 注册企业工厂的电子邮件地址。
Confirm E-mail Address 确认电子邮箱	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。
UFI 企业唯一识别码	A Unique Facility Identifier (UFI) that allows users to identify the user's facility through a unique number such as a DUNS number.
	企业的唯一识别码(UFI):用来识别用户企业的唯一码,例如 DUNS号码(邓白氏编码)。
UFI Temporarily Unavailable UFI暂无	Select if you are unable to provide a DUNS number. 如果您无法提供邓白氏编码,请选择此项。

Section 3 - Preferred Mailing Address Information (Optional)

第3部分-首选邮寄地址信息(选填项)

This section is optional but if your facility has a preferred mailing address then enter the information in Section 3 (Figure 8).

该部分不是必填项,但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(图8)。

Field 内容	Description 说明
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
街道地址第一行	工厂所在街道名称和地址号码
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。
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、省或领地。从下拉菜单选择工厂所在州、省或领地,如果不适用请选择"Not applicable"。

Field 内容	Description 说明
Telephone Number— Country (Optional)	For foreign registrations, the three-digit country code of the telephone number for the facility being registered.
电话一国家区号 (选填项)	海外注册企业输入三位数字的工厂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 facility being registered.
电话—地区代码	注册工厂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
(选填项)	境外企业)。
Telephone Number—	The telephone number of the facility being registered.
Phone Number (Optional)	注册企业工厂的电话号码。
注册企业电话号码	
(选填项)	
Telephone Number— Extension (Optional)	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。
(选填项)	
FAX Number—Country (Optional)	For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the facility being registered.
传真号码—国家区号(选填 项)	海外注册企业工厂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 facility being registered.
传真号码—地区号码 (选填 项)	注册工厂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	The telephone number of the FAX machine of the facility being registered.
(Optional)	注册企业工厂的传真号码。
传真号码(选填项)	
E-mail Address (Optional)	An electronic mail address for the facility being registered.
电子邮箱(选填项)	注册企业工厂的电子邮件地址。
Confirm E-mail Address (Optional)	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。
确认电子邮箱(选填项)	MM

Figure 8 – Section 3: Preferred Mailing Address Information 图8 - 第三部分: 首选邮寄地址信息

Is the preferred mailing address the same as the facility add Yes No	,	,		
		Clear	Autofill fr	om Account Informatio
Name	Telephone	e Number	(Optional)	
Name	Country	Area	Telephone	Ext
	Country	Агеа	Phone Number	Extension
Country/Area	Fax Numb	oer (Ontion	19/1	
Please Select a Country/Area	Country	Area	Fax	
Street Address, Line 1	Country	Area	Fax Number	
Silver Address, Ellie 1	E-Mail Ad	dress (Op	tional)	
Street Address, Line 2 (Optional)	Confirm E	-Mail Add	ress (Optional)	
Zip/Postal Code				
Please enter 'NONE' in Zip Code field if Zip Codes are not used				
in selected Country/Area				
City				
Please Select 🗸				
Please Select State/Province/Territory				

Section 4 - Parent Company Name/Address Information 第4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.

该部分不是必填部分,如果对企业适用或如果信息不同于第二部分或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 9);

注册企业工厂的所有者公司即总公司(图9)。

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

Field 内容	Description 说明
If information is the same as another section, check which section	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.
applies. 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. 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

Field 内容	Description 说明
	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。
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 autofill and decide the information is not what you wanted, you may clear and enter the correct information manually.
λ	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。
Company Name 企业名称	The name of the company that owns the facility being registered, if different from 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	The type of company, for example, "Company," Corporation," or "Limited."
企业名称后缀	企业类型,例如"Company"、"Corporation"或"Limited"。
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。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.
街道地址第一行	工厂所在街道名称和地址号码。
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。
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"。

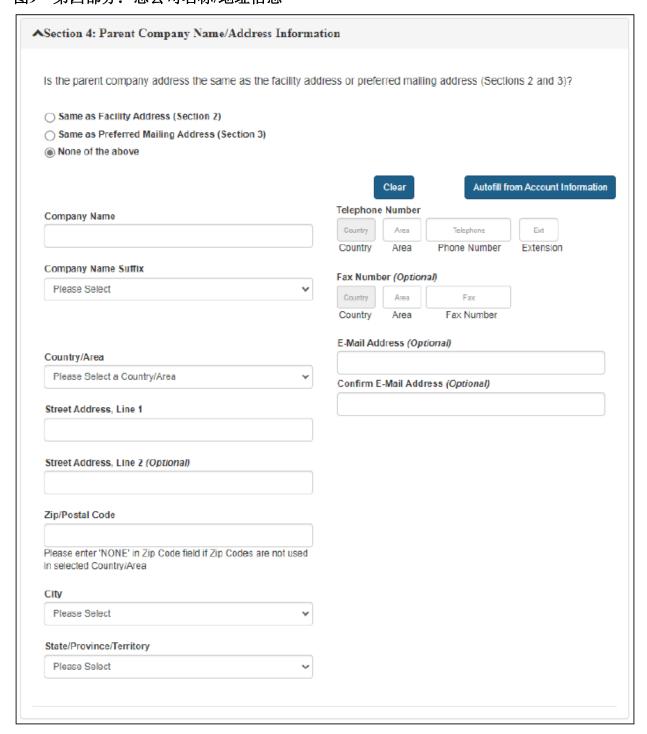
Field 内容	Description 说明
City 城市	The city in which the parent company is located.
	总公司所在城市。
State/Province/Territory 州/省/领地	The state, province, or territory in which the parent company is located. Select a state, province, or territory from the pull-down menu when applicable or select "Not applicable."
	总公司所在州、省或领地。从下拉菜单选择工厂所在州、省或领地,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.
电话一国家区号 (选填项)	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 (选填项)	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	
(选填项)	
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。
(选填项)	
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 项)	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 项)	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 Number (Optional) 传真号码(选填项)	The telephone number of the FAX machine of the parent company. 总公司的传真号码。

Field 内容	Description 说明
E-mail Address (Optional) 电子邮箱(选填项)	An electronic mail address for the parent company. 总公司的电子邮件地址。
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。

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 ..."

如果企业使用与第二部分"企业名称/地址信息"中填写的企业名称不同的名称来经营业务,请务必在此部分注明其他在贸易过程中使用的名称。例如,如果您的企业设施可以描述成"也作为······来经营"或"该企业也被称作······",请填写本部分。

Figure 9 – Section 4: Parent Company Name/Address Information 图9 – 第四部分: 总公司名称/地址信息



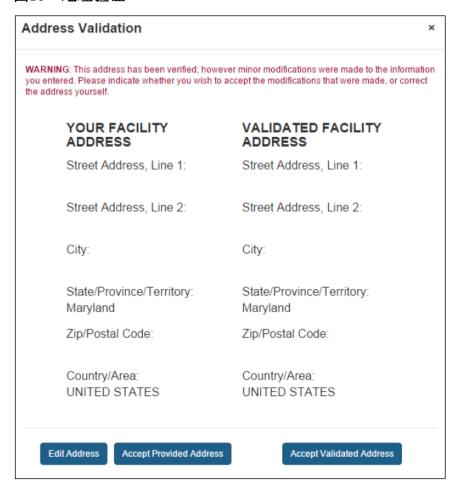
After completing the Section 2, Section 3 and Section 4, the system performs address validation for the addresses entered in Section 2 and Section 3 when the user clicks "Next" button.

完成第二部分、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 10).

注意: 若收到"工厂地址无效"或"地址已被更正"的提示信息,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)",然后继续注册程序(图10)。

Figure 10 - Address Validation 图10 – 地址验证



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 11). 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: 如果您在地址被验证后收到如下提示,意味着系统认为您正在创建的新注册可能和一个已有注册重复(图11)。您可以继续创建您的新注册,但请注意您的注册已被标注,FDA将会审核。

Figure 11 – Possible Duplicate Registration 图11 – 可能的重复注册



Section 5 - Facility Emergency Contact Information 第5部分-企业紧急联系信息

Enter the Facility Emergency Contact Information (Figure 12). 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(图12)。紧急情况下FDA会使用此信息通知企业。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。如果您注册的是海外企业工厂,系统会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

Field 内容	Description 说明
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 (选填项)	The First name of the emergency contact person. 紧急联系人的名。
Middle Name (Optional) 中间名(选填项)	The Middle name of the emergency contact person. 紧急联系人的中间名。
Last Name (Optional) 姓氏(选填项)	The Last name of the emergency contact person. 紧急联系人的姓氏。
Job Title (Optional) 职务(选填项)	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—国家区号	For foreign registrations, the three-digit country code of the telephone number for the facility being registered. 海外注册企业输入三位数字的工厂所在国家的电话区号。

Field 内容	Description 说明
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.
电话一地区代码	注册工厂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— Phone Number	The telephone number of the emergency contact. 紧急联系人的电话号码。
注册企业电话号码	
Telephone Number— Extension	The telephone extension, if any, dialed after the telephone number, of the emergency contact. 紧急联系人的电话如果有分机号,请填写分机号。
电话号码—分机号 E-mail Address 电子邮箱	An electronic mail address for the emergency contact. 紧急联系人的电子邮件地址。
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。

Figure 12 - Section 5: Facility Emergency Contact Information

图12 - 第五部分: 企业紧急联系信息

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Section 6 - Trade Names

第6部分-商业名称

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 13).

如果该企业使用除第二部分中列出的企业名称之外的商业名称,您可以在"第六部分:商业名称"中填写(图13)。

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

Field 内容	Description 说明
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.
另外的商业名称	如果该企业使用除第二部分中列出的企业名称之外的商业名称,您可以在此处输入该名称。

Figure 13 - Trade Names 图13 – 商业名称

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 Section 2: Facility Name/Address Information? Yes No
Alternate Trade Name #1
Alternate Trade Name #2
Alternate Trade Name #3
Alternate Trade Name #4

Section 7 - United States Agent 第7部分-美国代理

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

海外企业注册必须完成此部分。

Enter information about the United States Agent for the facility being registered (Figure 14). 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.

输入注册企业美国代理的信息(图14)。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(美国境内企业不要求必须有美国代理)。用户进行继续注册操作后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: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, 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,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的企业信息自动导入 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。
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。

Field 内容	Description 说明
您是个人、合伙企业、公司、还 是协会?	
Title (optional) 称谓(选填项)	The title of the U.S. Agent 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.
Middle Name 中间名	海外注册企业美国代理人的名字。 The middle name of the person acting as U. S. Agent for the foreign facility being registered.
11974	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.
Country/Area 国家/地区	海外注册企业美国代理人的姓氏。 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 街道地址,第一行	The street name and address number of the U.S. Agent. 美国代理所在街道名称和地址号码。
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。
Zip Code 邮政编码	The zip code for the U.S. address of the U.S. Agent. 美国代理美国地址的邮政编码。
City 城市	The city in which the U.S. Agent is located. 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"。

Field 内容	Description 说明
Telephone Number Area/City Code	The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the U.S. Agent.
电话号码 地区/城市代码	美国代理电话号码中的三位数字的地区代码(美国境内地址)或城市代码(美国境外地址)。
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(一天24小时、一周7天)联系到的美国代理电话。
Fax Number — Country/Area/Phone Number (optional) 传真号码 — 国家/地区/电话号码 (选填项)	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(一天24小时、一周7天)联系到的美国代理传真号码。
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。
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。

Figure 14 - United States Agent 图14 – 美国代理

Section 7: United States Agent				
Note: If you modify this address, please review the ad	ddress in Section(s) 1	1 to verif	that those address	sses are still correct.
(To be completed by facilities located outside any the Commonwealth of Puerto Rico)	State or Territory o		ted States, the Di	istrict of Columbia, or
If you are assigning a new US agent please select Yo agent please select No.	es. If you are simply co	hanging t	he name or addre	ss of your current US
(Note: Registration number and PIN will be mailed to	your new U.S Agent i	f you sel	ect Yes.)	
○ Yes ● No				
	Clear		Autofil	I from Account Information
Are you an individual, partnership, corporation, or associ	ation?			
Please Select	~			
Title (Optional)	Telephone	e Number		
	001	Area	Telephone	Ext
From Name :	Country	Area	Phone Number	Extension
First Name	Emergeno	y Contact	Telephone Number	
	001	Area	Telephone	
Middle Name (Optional)	Country	Area	Phone Number	
	Fax Numb	er (Option	nal)	
Last Name	001	Area	Fax	
	Country	Area	Phone Number	
	E-Mail Ad	dress		
Country/Area				
UNITED STATES	Confirm E	-Mail Add	ress	
Street Address, Line 1				
Street Address, Line 2				
Zip Code				
Please enter 'NONE' in Zip code field if Zip codes are not use	din			
selected Country/Area	2 111			
City				
Please Select	•			
State/Province/Territory				
Please Select	~			

Section 8 - Seasonal Facility Dates of Operation (Optional)

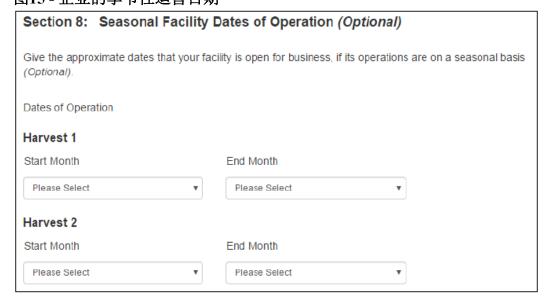
第8部分 - 企业的季节性运营日期(选填项)

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 15).

如果企业季节性运营,请注明企业工厂运营的大致日期。您最多可以选填两个不同的 采收时段(每个时段包括开始和结束月份)(图15)。

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. Select Start Month and End Month.		
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。 选择开始月份和结束月份。		
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。		

Figure 15 - Seasonal Facility Dates of Operation 图15 - 企业的季节性运营日期



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 as shown in (Figure 16).

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(如图16所示)。

This section is required. 该部分必填。

Figure 16 - General Product Categories 图16 - 一般产品类别

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 – 一般产品类别 – 供人类食用的食品;以及企业设施的活动类型

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.

所有注册企业必须完成第9a或9b部分或两部分都完成(如适用)。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.

如果您的企业不生产、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"。您可以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.

企业活动类型为选填项。您可以根据企业实际从事的生产相关活动,选择生产/加工、包装或存储食品的所有活动类型。例如,如果选择产品类别"酒精饮料alcoholic beverages,#1",您的企业为"生产/加工商manufacturer/processor",您需要在第八栏第二行选择该选项。

"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.

"全选"和"取消全选"项可以让用户一次性选择或取消选择全部选项。

Examples for Section 9a (Figure 17 and Figure 18).

第9a部分的例子(图17和图18)

Figure 17 - Section 9a: General Product Categories 图17 - 第9a部分: 一般产品类别

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 18 - Section 9a: General Product Categories, Cont.

图18-第9a部分:一般产品类别(续)

YPE OF ACTIVITY CONDUCTED AT THE FAC anufacturing/processing, packing or holding o	ILITY. Check all types of operations that are performed at food.	this facility regarding the
Selected Product Name	Select Activity Types	
12. DIETARY SUPPLEMENT CATEGORIES		
b. Vitamins and Minerals	None selected ▼	
Other Activity Conducted		

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

第9b部分 – 一般产品类别 – 供动物食用的食品;以及企业的活动类型

Select as many of the 32 categories as appropriate. 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。如果没有适合的选项,请勾选33项:"上述食品类别都不适用"。您可以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.

"全选"和"取消全选"项可以让用户一次性选择或取消选择全部选项。

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:关于食品企业注册过程中食品类别使用的更多信息,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)。

Examples for Section 9b (Figure 19 and Figure 20).

第9b部分的示例(图19和图20)。

Figure 19 - Section 9b: General Product Categories

图19-第9b部分:一般产品类别

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

Figure 20 - Section 9b: General Product Categories Cont.

图20 - 第9b部分: 一般产品类别(续)

Section 9b: General Product Categories - Food for Animal Consumption; and Type of Activity Conducted at the Facility					
manufacturing/processing, pa		•			
Selected Product Name 1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)	Select Activity Types None selected →				
Other Activity Conducted		<u> </u>			

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

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 21).

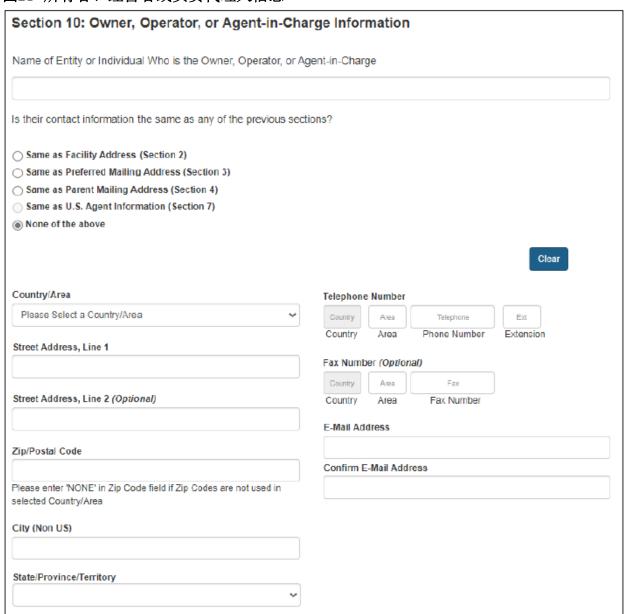
如果所有者、经营者或负责代理人的联系方式信息与本表的其他部分相同,选择该部分对应的圆圈,否则请按要求填写信息(图21)。

Field 内容 Description 说明 Name of Entity or Individual 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 who is the Owner, Operator, charge address information is identical to previously entered information. If you or Agent in charge. If choose one of these and decide the information is not what you wanted, you may information is the same as clear and enter the correct information manually. 注册企业的所有者、经营者或 another section of the form, 负责代理人的名称(机构)或姓名(个人)。明确所有者、经营者或负责 check which section. 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 所有者、经营者或负责代 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。 理人的名称(机构)或姓 Choose Section 2 if the owner, operator, or agent in charge address information is 名(个人)。如果该信息 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 与本表中其他部分相同, charge address information is the same as the preferred mailing address 请查看是哪部分。 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。 - 或-

Field 内容	Description 说明
	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-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-如果您需要输入新信息,请选择"None of the above(以上都不选)"。
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 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。
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.
עוני יויי	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
79416	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.

Field 内容	Description 说明
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数 国家号。
Telephone Number – Area	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.
电话 – 区号	注册企业所有者、经营者或负责代理人电话号码的三位数区号(美国国内地址)或城市号(美国国外地址)。
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	The telephone extension, if any, dialed after the telephone number, 在电话号码之后拨打的分机号(如有)。
电话分机号 	
Fax Number –Country (optional)	For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered.
传真- 国家号(选填)	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数国 家号。
Fax Number –Area (optional) 传真 – 区号(选填)	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传真号码的三位数区号(国内地址)或城市号(国外地址)。
Fax Number –Fax Number (optional)	The FAX number of the owner, operator, or agent in charge of the facility being registered
传真号 (选填)	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。
Confirm E-mail Address	Confirm the email address entered. The E-Mails must match.
(Optional) 确认电子邮件(选填)	确认输入的电子邮件地址。两次输入的电子邮件地址必须一致。

Figure 21 - Owner, Operator, or Agent-in-Charge Information 图21 - 所有者、经营者或负责代理人信息



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 22).

勾选方框,确认已知晓: FDA可以依据《联邦食品、药品和化妆品法》的规定,在合适的时间、以合适的方式对企业进行检查(图22)。

Figure 22 - Inspection Statement

图22 - 检查声明

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 23 and Figure 24). 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.

输入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(图23和图24)。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.

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。 If option B is selected then a screen will pop up and all the details have to be filled. 如果选择B选项,则屏幕会弹出对话框,对话框内的详细信息都需要填写。

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.

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。

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

Field 内容	Description 说明
Check Box 勾选项	The Secretary will be permitted to inspect facility at the time and in the manner permitted by this act.
120	允许美国卫生与人类服务部部长根据法律允许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 此表提交人的姓名
Select option to 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:
选择说明准授权您提交此注 册的选项	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) –
	If you checked box B above (Individual Authorized to Submitthe 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人(在下面填写地址)
	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:
	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 -
	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)。

Field 内容	Description 说明		
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		
1,74,44	代表所有者、经营者或负责代理人授权注册的个人姓名		
Country/Area	The country/area in which the Authorizing Individual is located		
国家/地区	授权人所在国家/地区		
Street Address, Line 1	The street name and address number of the Authorizing Individual		
街道地址第1行	授权人地址中的街道名称和号码		
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。		
Zip /Postal Code	The zip code for the U.S. address of the Authorizing Individual		
邮编	授权人美国地址的邮编		
City	The city in which the Authorizing Individual is located.		
城市	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."		
	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)"。		
Telephone Number – Country	The Country code (for foreign addresses) of the telephone number for the Authorizing Individual.		
电话 – 国家号	授权人电话号码的国家号(国外地址)。		
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	授权人电话号码的三位数区号(美国国内地址)或城市号(美国国外地址)。		
Telephone Number –	The telephone number of the Authorizing Individual.		
Phone Number	授权人的电话号码。		
电话号码			
Telephone Number –Extension 电话 – 分机号	The telephone extension, if any, dialed after the telephone number, Authorizing Individual.		
	授权人电话号码的分机号(如有)。		

Field 内容	Description 说明
Fax Number–Country (optional)	The Country code (for foreign addresses) of the FAX machine for the Authorizing Individual.
传真- 国家号(选填)	授权人传真号的三位数国家号(国外地址)。
Fax Number–Area (optional)	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-区号(选填)	授权人传真号码的三位数区号(美国国内地址)或城市号(美国国外地址)。
Fax Number – Fax Number (optional) 传真号(选填)	The telephone number of the Fax machine of the Authorizing Individual. 授权人的传真号码。
E-mail Address 电子邮件	The electronic mail address of the authorizing individual. 授权人的电子邮件地址。
Confirm E-mail Address (Optional) 确认电子邮件(选填)	Confirm the email address entered. The E-Mails must match. 确认输入的电子邮件信息。两次输入的电子邮件必须一致。

Figure 23 - Certification Statement

图23 - 保证声明

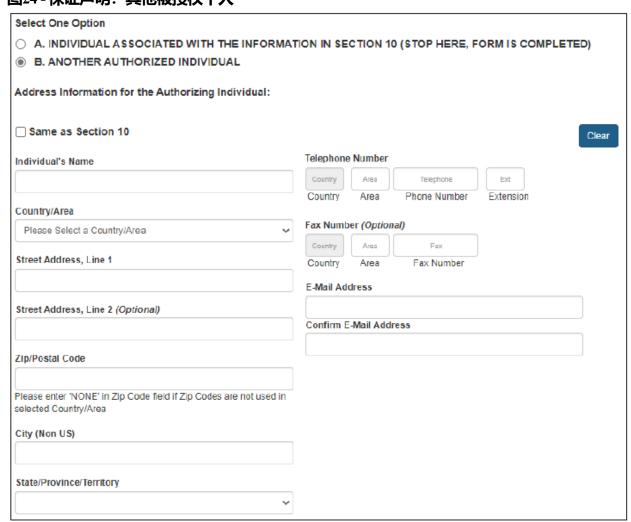
Section 12: Certification Statement

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.

makes a ma	terially raise, lictitiou	s, or fraudulent st	atement to the o.s
Name of the	Submitter		
Select One	Ontion		

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

Figure 24 - Certification Statement: Another Authorized Individual **图24 - 保证声明: 其他被授权个人**



Registration Review

注册信息检查

Review your registration before submitting it for processing. (Figure 25, 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25, 部分显示)选择"Edit (编辑)" 按钮,可以弹出相应的信息输入屏幕以进行编辑和保存修改。

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

选择"提交(Submit)"提交注册或"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: "第1部分:注册类型"中的企业工厂所在地(在此填写是美国国内还是美国国外工厂)在这个阶段是不能修改的。如果您想修改工厂所在地,您必须取消此注册,重新进行注册。

Figure 25 - Registration Review 图25 - 注册信息检查

✓Section 1 ✓Section 2-4 ✓Section 5-7 ✓Section 8-9	Section 8a-9b Section 10 Section 11-12 Review
Please review your registration. If all information To make changes to a section, click the Edit but Date	
Created Date	
Registration Status	
Registration Status Reason	
Is this facility engaged in the manufacturing/processing, packing, United States? (a) Yes (b) No	or holding of food for human or animal consumption in the
Section 1: Type of Registration	
Facility Location: Domestic Registration	
Are you the new owner of a previously registered facility?	
○ Yes ® No	
Previous Owner's Title: Pravious Owner's Name: Previous Owner's Registration Number:	
Section 2: Facility Name/Address Information) Edit
Facility Name	Telephone Number
Facility Name Suffix	Fax Number
Facility Street Address, Line 1	E-Mail Address
Facility Street Address, Line 2	
City	
State/Province/Territory	
Zip/Postal Code	
Country/Area	
Section 3: Preferred Mailing Address Informa	ation / total
Complete this section if different from Section 2 Facility Name/A	ddress Information (OPTIONAL)
is the preferred mailing address the same as the facility address	
Name	Telephone Number
Address, Line 1	Fax Number E-Mail Address
Address, Line 2	L-mus rule 000
City	
State/Province/Territory	
Zip Code (Postal Code)	
Country/Area	

Registration Successful

注册成功

A message indicates that your registration was submitted successfully, and your Registration Number, PIN and your registration's expiration date are displayed (Figure 26). Record these numbers for your records.

页面将显示注册提交成功的提示信息,以及您的注册号、密码和注册有效期(图 26)。请记录这些信息备以后查用。

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.

如果您计划由另一个账户所有人更新注册信息,您可以把注册号和密码告知此人以进行登录。但是请注意:把您的注册号和密码告知此人意味着此人也可以注销该注册。

View Complete Registration

查看完整注册

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.

要查看整个注册的最终版,请选择"查看完整注册(View Complete Registration)"。使用屏幕下方的按钮选项,您可以把注册打印出来备用。或者您可以回到FFRM主菜单(Main Menu)进行另一个注册或完成其他注册相关任务。

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

注意: 注册号和密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

Field 内容	Description 说明	
Registration Number	The number assigned by FDA to this facility's registration	
注册号	FDA分配的企业的注册号码	
PIN	The Personal Identification Number for this facility's registration	
密码	该企业注册的个人身份识别码	
Registration Expiration Date	The date your facility's registration will expire	
注册有效期	您的企业注册失效的日期	

The system displays this message only if it is Domestic Registration submitted by Owner Operator (Figure 26). Otherwise, a different message is displayed (Figure 27).

只有企业所有者经营者提交的美国国内企业注册,系统会显示此信息(图26)。其他情况下将显示不同的提示信息(图27)。

Figure 26 - Registration Submitted - Domestic Registration submitted by Owner Operator 图 26 - 注册已提交- 所有者经营者提交的美国国内企业注册

Registration Successful 🗸

Your Registration Number is

Your Pin is

Your registration's expiration date is

Please keep the registration number and PIN for your records. The registration number is required for all communications with FDA regarding this registration. The PIN will allow you to access a registration online, if the registration was initially submitted as a paper form. Please refer to the help section for more details.

View Complete Registration

Figure 27 - Registration Submitted

图27-注册已提交

Registration Submitted - Verification Pending

In accordance with 21 CFR 1.231(a)(b) 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 – 保存已部分完成的注册信息

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,系统将允许用户将注册信息保存为草稿。这样您就可以保存部分完成的注册信息,之后再继续完成注册。

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,否则您所保存的注册信息草稿将被从系统里删除。

When you choose "Save and Exit", the system will advise you that a reference number has been assigned (Figure 28). This is temporary and may be used as a reference to complete your registration.

当您选择"保存并退出(Save and Exit)"时,系统将提示您已分配了一个参考号码(图28)。这是临时号码,可以在完成注册的过程中查找使用。

Figure 28 - Draft Confirmation 图28 - 注册草稿保存确认

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 screenshot 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.

要进入注册草稿,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 29).

在选择"完成注册草稿(Complete Draft Registration)"按钮选项后,系统将显示您可以完成的所有注册草稿(图29)。

Figure 29 - Complete Draft Registration 图29 - 完成注册草稿

Complete Dra	ft Registration		
registration for upda	te to complete the draft registration.	s. Please click on a reference code to select a	
Show 25 v er	ntries		
Reference Li	Facility Name	Facility Address	11
47256			
Showing 1 to 1 of	f 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 30). 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.

点击参考号码,选择您想完成编辑的草稿。系统会显示该注册之前已经输入的所有信息(图30)。可以选择您想完成的部分旁边的"编辑(Edit)"选项。系统将引导您完成注册剩下的部分。

Figure 30 - Review Registration 图30 – 注册预览

✓Section 1	✓Section 2-4	✓Section 5-7	✓Section 8-9	✓Section 9a-9b	✓Section 10	✓Section 11-12	Review
Please review your registration. If all information is correct, click the Submit button below. To make changes to a section, click the Edit button for that section. Date Created by							
Created Dat	in a						
Registration	Status						
Registration	Status Reason						
is this facility en United States? ⊕ Yes ○ N		anufacturing/pro	cessing, packing	, or holding of fo	od for human o	r animal consumpl	tion in the
Section 1:	Type of Re	gistration					
Facility Locat	ion: Domestic	Registration					
Are you the n	ew owner of a p	reviously registe	red facility?				
O Yes ⊕ No							
Previous Owi Previous Owi Previous Owi		n Number:					
Section 2:	Facility Na	me/Addres	s Informatio	on			✓ Edit
Facility Name	э			Telephone N	lumber		
Facility Name	e Suffix			Fax Number E-Mail Addre			
Facility Stree	t Address, Line	1		E-Mail Addre	155		
Facility Stree	t Address, Line	2					
City							
State/Province	ce/Territory						
Zip/Postal Co	ode						
Country/Area	3						
Section 3:	Section 3: Preferred Mailing Address Information						
Complete this	section if differe	ent from Section	2 Facility Name	Address Informa	ition (OPTIONA	AL)	
	ed mailing addre	ss the same as t	the facility address	ss (Section 2)7			
Name				Telephone N	lumber		
Address, Line	e 1			Fax Number E-Mail Addre			
Address, Line	e 2			L-Mail Addre	,00		
City							
State/Province/Territory							
Zip Code (Postal Code)							
Country/Area							