Food Facility Registration User Guide: Step-by-Step Instructions 食品企业工厂注册的用户指南:分步骤说明

Online Registration of Food Facilities 食品企业的网上注册 https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities

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Register a Food Facility

食品企业工厂注册

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) 用户在登陆美国食品药品管理局(FDA)的行业系统(FIS)后,如下图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"食品企业工厂注册(Food Facility Registration)"的选项。

Figure 1

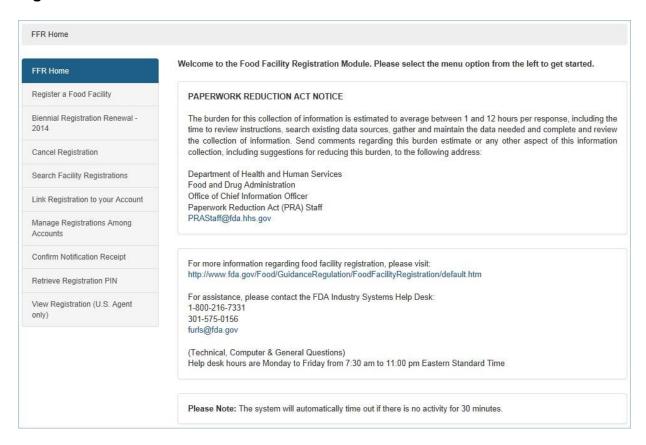
| Account Manageme | nt | | 0 🖨 |
|-------------------------|--|--|-----|
| Account Management | | | |
| Edit Account Profile | Welcome to the FDA Industry Systems. You are lo | gged in as for | |
| Change My Password | You may choose an option on the left to manage your account or select an FDA syst To obtain access to available FDA systems, choose the Update System Access op | | DA |
| Update System Access | system to your account. | | |
| Create a Subaccount | CFSAN - Center for Food Safety and Applied Nutrition | N. | |
| Deactivate a Subaccount | Click to launch the Application(s) | | |
| Reactivate a Subaccount | ✓ Food Facility Registration | Certificate Application Process | |
| | Acidified/Low-Acid Canned Foods Registration and Process Filing | ✓ Structure/Function Claims Notification | |
| | ☐ Shell Egg Producer Registration | ✓ New Dietary Ingredient Notification | |

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所示在主菜单中选择"注册一家食品企业 (Register a Food Facility)"。从主菜单中,您也可以进行初始注册,更新现有注册,取消企业注册,搜索您之前完成的某个注册,管理账户的注册,链接注册信息到

您的账户,确认收到信件通知,找回丢失或遗忘的PIN唯一码,并可在两年更新期内进行两年一次的注册更新。

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Figure 3所示,在每一页的顶部有一个状态栏来显示你在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。如果需要查看所有的帮助文件,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 Home(FURLS首页)"链接可以回到FIS/FURLS首页(如Figure 1),点击"FFR Home(FFR首页)"可以回到食品企业注册主菜单(如Figure

2)。点击"FURLS Home (FURLS首页)"来退出账户登陆。

Figure 3



Each screen also includes navigation buttons such as the following (Figure 4): 每一页也包含以下浏览按钮(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-返回上一页面继续输入注册信息。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)
- 保存和退出-保存尚未填写完整的注册。(详情参见"保存和退出-保存未填写完整的注册表)

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。如果您是第一次注册,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 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? O 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.

针对以上问题无论您选择的答案是什么,您都可以继续您食品企业工厂的注册。您也可以在注册信息查验页面上查到您对以上问题的答复。

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? 该工厂是否从事食品的生产/加工、包装或储存,这些食品是用来供应在美国的人或动物食用的。 | 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、并不储存这些食品,请选择"No(不是)"。 |
|---|--|
| Are you a broker, distributor, importer/filer? 您是否是经销商、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"Yes(是)"。 |
| 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- 注册类别

This section is required.

此部分内容必填。

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,您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

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

| Facility Location 工厂所在地 | 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. 明确工厂位于美国境内还是美国境外。 从以下两个选项中选择: 美国国内注册-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? 您是否是已注册 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. 如果您是作为之前注册过的企业的新所有者来提交申请,请选择"是"。 如果你正在提交从来没有注册过的企业注册申请,请选择"否"。 |
| Previous owner's title (optional) 原所有者的称呼 (选填) | 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. 请为从以下选项为原所有者选择一个称呼(先生、夫人、小姐、女士、博士、其他)。如果选择"其他",系统会让您手动输入合适的称呼。 |
| Previous owner's name (optional) 原所有者姓名 (选填) | If you are a new owner of a previously registered facility, provide the name of the previous owner of the facility, if known. 如果您是之前注册过的企业的新所有者,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) | 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对每个注册企业工厂都会分配一个注册号码。 如果您是之前注册过的企业的 |

新所有者,请提供之前所有者注册该企业工厂时的注册号(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信并要求其确认,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进行变更。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 registration to your enterprise account? 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

如果该账户是子账户,那么用户可以选择是否自动链接其账户到该注册。

您是否想要把该

注册链接到你的

企业账户

Section 2 - Facility Name / Address Information

第2部分-企业工厂名称/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.

输入注册企业工厂名称和地址。如果首选邮寄地址不同于工厂地址,您可以选择输入首 选邮寄地址。

This section is required.

此部分内容必填。

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

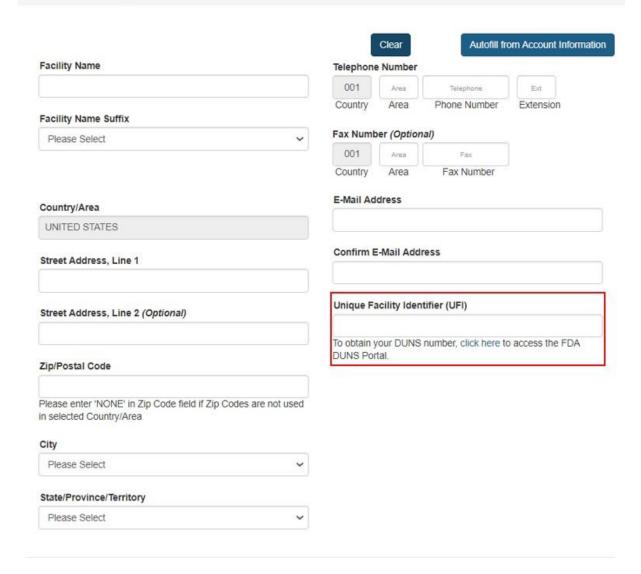
输入注册企业工厂的名称、地址、电话号码、传真号码和需要注册的企业工厂的邮箱地址。(见Figure 6a)

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.

如果您希望系统自动使用您在创建线上管理账户(Online Account Administration)时填写的工厂信息,您可以选择"Autofill from Account Information"选项,系统会自动调用您之前录入的信息。选择"Clear"来清除已输入信息。

Figure 6a

^Section 2: Facility Name/Address Information



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

| Facility Name | The name of the facility being registered. |
|------------------------------------|---|
| 企业工厂名称 | 需要注册的工厂名称 |
| Facility Name Suffix | The type of company, for example, "company," "corporation," or "limited." |
| 企业工厂名称后缀 | 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。海外工厂注册请从下拉菜单中选择国家/地区。(对于美国国内工厂的注册,系统会自动填选美国。) |
| Street Address, Line 1 | The street name and address number |
| 详细地址第1行 | 工厂所在街道名称和号码 |
| 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. 第二行街道名称和号码(若第一行未写完)。还可以输入其他具体地址信息,例如门牌房间号码。 |
| 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/区域 | 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/区域。从下拉菜单中选择工厂所在州、省或区域,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 086) |

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

Section 3 - Preferred Mailing Address Information (Optional) 第3部分-首选邮寄地址信息 (选填)

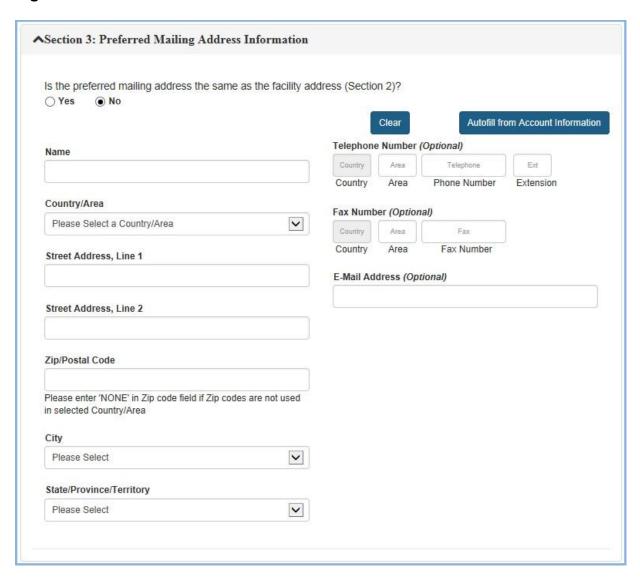
This section is optional but if your facility has a preferred mailing address then enter the information in Section 3 (Figure 6b).

此部分是选填部分,但是如果您企业的首选邮寄地址不同于工厂地址,请在第3部分输入该信息。详见Figure 6b

| Name 名称 | The name of the facility being registered. 需要注册的工厂名称 |
|--|--|
| 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。海外工厂注册请从下拉菜单中选择国家/地区。(对于美国国内工厂的注册,系统会自动填选美国。) |
| Street Address, Line 1 详细地址第1行 | The street name and address number 工厂所在街道名称和号码 |
| 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. 第二行街道名称和号码(若第一行未写完)。还可以输入其他具体地址信息,例如门牌房间号码。 |
| 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/Territor y 州/省/区域 | 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/区域。从下拉菜单中选择工厂所在州、省或区域,如果 |

| | 不适用,请选择 "Not applicable" 。 |
|---|--|
| Telephone Number (Optional) Country 电话-国家区号(选填) | 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 (选 填) | The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the facility being registered. 美国国内企业注册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) 电话 (选填) | The telephone number of the facility being registered. 注册企业工厂电话。 |
| Telephone Number Extension (Optional) 电话号码-分机号 (选 填) | The telephone extension, if any, dialed after the telephone number, of the facility being registered 注册工厂如果有分机号,请填写分机号。 |
| FAX Number (Optional) Country 传真号-国家区号 (选 填) | For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the facility being registered 海外注册工厂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(选填) | 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. 美国国内注册工厂请填写传真机拨号号码的三位数字地区号码,海外企业请填写注册工厂的传真机拨号号码的城市代码。 |
| FAX Number (Optional) FAX Number 传真号码(选填) | The telephone number of the FAX machine of the facility being registered. 注册工厂的传真机拨号号码。 |
| 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.

此部分是可选填部分,如此部分内容对企业适用,且信息不同于第2部分和第3部分已输入的信息,请在此部分输入。

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

注册工厂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,并确定系统自动填入的信息不是您想输入的信息,您可以选择"Clear"来清除系统已填入信息,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2部分输入的企业工厂名称/ 地址信息一致,请选择"Same as Facility Name/Address Information (Section 2)",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3部分"首选邮寄地址信息"中输入的信息一致,请选择"Same as Preferred Mailing Address (Section 3),或 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/地址与之前输入的工厂名称及地址和首选邮寄地址都不相同,请选择"None of Above" Choose Clear if you need to clear Section 4 若清除第四部分已输入内容,请选择"Clear" |
|---|
| 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。 |
| 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(总公司)的名称。 |
| 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" |
| 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。对于海外注册工厂,请从下拉菜单选择 |
| |

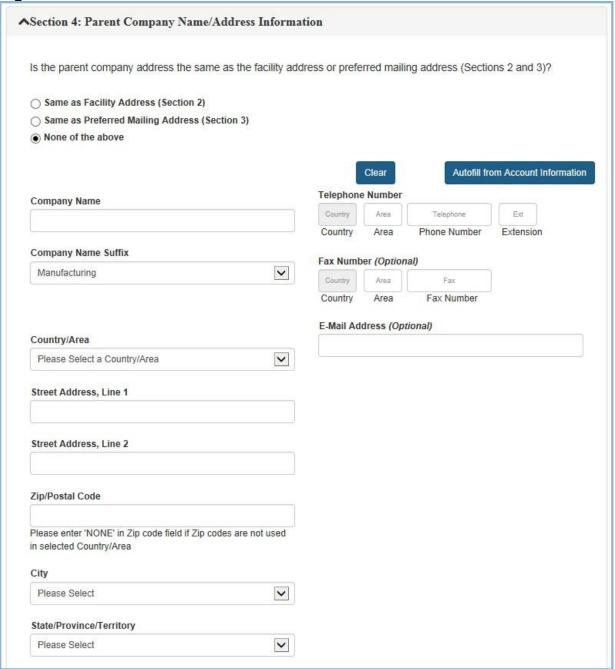
| | 所属国家/地区。(对于美国国内注册工厂,系统自动默认填写 美国) | | |
|---|---|--|--|
| Street Address, Line 1 详细地址第1行 | The street name and address number. 工厂所在街道名称和号码 | | |
| Street Address, Line 2 详细地址第2行 | The second street name and address number, if applicable. May also enter information such as Suite number. 第二行街道名称和号码(若第一行未写完)。还可以输入其他具体信息例如门牌房间号码。 | | |
| 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 城市 | The city in which the parent company is located. 总公司所在城市。 | | |
| State/Province/Territory 州/省/区域 | 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/区域。从下拉菜单选择总公司所在州、省或者区域,如果不适用请选择 "Not applicable"。 | | |
| Telephone Number Country (Optional) 电话-国家区号(选 填) | For foreign registrations, the three-digit country code of the telephone number for the parent company. 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) 电话-地区代码(选 填) | The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the parent company. 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。 The telephone number of the parent company. | | |
| Phone Number | 总公司电话号码。 | | |

| (Optional) 电话号码(选填) | |
|---|---|
| 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. 总公司如果有分机号,请填写分机号。 |
| FAX Number (Optional) Country 传真号码-国家区号(选 填) | For foreign registrations, the three-digit country code of the telephone number of the FAX machine for the parent company. 海外注册企业的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(选填) | 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(选填) | 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(选填) | 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2部分"企业名称/地址"中填写的企业名称来经营业务,请在此部分注明其在贸易过程中使用的其他名称。例如,如果您工厂"也使用。。。来经营",或"该工厂也被称作。。。"等,则请填写该部分。

Figure 6c



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

注:填写完成第2部分、第3部分和第4部分的联系信息内容后,当用户点击"NEXT (下一步)"时,系统会对第2部分和第3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: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

Edit Address

×

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

Accept Validated Address

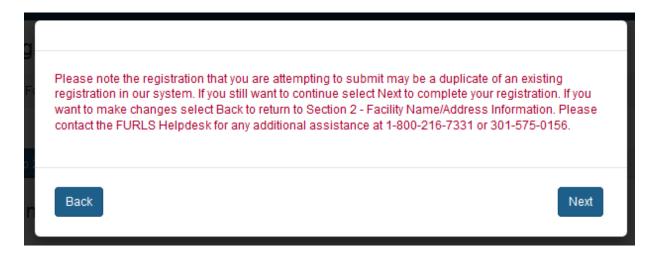
Note: If you receive the following message after your address has been validated, then the system has determined that the new registration that you are attempting to create may be a possible duplicate to an existing registration (Figure 7b). While you may continue to create your new registration, please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

Accept Provided Address

注: 如果在系统验证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(详见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: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 8。

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5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.

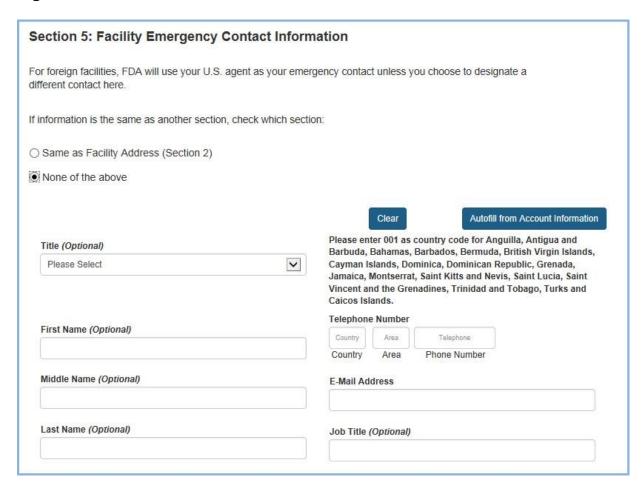
输入企业紧急联系信息(Figure 9)。如遇紧急情况FDA会用此信息来通知企业。除非海外注册企业选择另外指定紧急联系人,FDA一般会使用该企业的美国代理作为紧急联系人。如果您在注册海外工厂,系统会自动提示让您选择是否使用美国代理联系信息作为您的紧急联系信息。

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 (选填) | The First name of the emergency contact person. 紧急联系人的名。 |
| Middle Name (Optional) 中间名(选填) | The Middle name of the emergency contact person. 紧急联系人的中间名。 |
| Last Name (Optional) 姓氏(选填) | The Last name of the emergency contact person. 紧急联系人的姓氏。 |
| Job Title (Optional) 职务 (选填) | 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 海外企业输入注册工厂所在国家的电话区号(三位数字:例如中国为086) |
|--|---|
| Telephone Number Area 电话-地区号码 | 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 电话号码 | The telephone number of the emergency contact. 紧急联系人电话号码。 |
| Telephone Number Extension 电话-分机号码 | The telephone extension, if any, dialed after the telephone number of the emergency contact. 紧急联系人的电话分机号码。 |
| E-mail Address 邮件地址 | An electronic mail address for the emergency contact. 紧急联系人的电子邮件地址。 |

Figure 9



Section 6 - Trade Names

第6部分-贸易名称

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).

如果该工厂使用除第2部分中列出的名称之外,在贸易过程中还使用其他名称,您可以把它列入第6部分:贸易名称 (Figure 10)。

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

Alternate Trade Name 贸易中使用的其他名称

If this facility uses alternate trade names in addition to the name provided in Section 2, you can enter the names here如果该工厂使用除第二部分中列出的名称之外,在贸易过程中还使用其他名称,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 Section 2: Facility Name/Address 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7部分-美国代理

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

此部分是海外注册工厂的必填部分。

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.

输入注册工厂在美国的代理人信息(Figure 11)。每个海外企业工厂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来进入下一步注册。

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: 美国代理不应与代理负责人混淆。代理负责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工厂,系统不会自动导入信息。如果您的账户不是第一次注册企业工厂,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) 称谓(选填) | 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. 海外注册企业工厂美国代理人的名字。 |
| Middle Name 中间名 | The middle name of the person acting as U. S. Agent for the foreign facility being registered. 海外注册企业工厂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. 海外注册企业工厂美国代理人的姓氏。 |
| 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 详细地址第1行 | The street name and address number of the U.S. Agent. 美国代理所在街道名称和号码。 |
| 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. 第2行街道名称和号码(若第一行未写完)。还可以输入其他具体信息例如门牌房间号码。 |
| 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/区域 | 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/区域。从下拉菜单选择美国代理所在州、省或者区域,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. 美国国内地址请填写三位数字的电话地区代码,海外地址请填写城市电话代码。 |
| 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)的美国代理电话。 |
| Fax Number(optional) Country/Area/Phone Number | The FAX number of the U. S. Agent that FDA can call 24 hours a day, 7 days a week, in case of emergency. |
| 传真号码(选填) 国家/地区/传真机电话号码 | 如有紧急情况,FDA可以随时联系(一天24小时,一周7天)的 美国代理传真机号码。 |
| 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。 |

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 No Clear Autofill from Account Information Are you an individual, partnership, corporation, or association? Please Select ~ Title (Optional) Telephone Number 001 Area Telephone Ext Country Area Phone Number Extension First Name **Emergency Contact Telephone Number** 001 Middle Name (Optional) Country Phone Number Fax Number (Optional) 001 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 V Please Select State/Province/Territory V Please Select

Section 8 - Seasonal Facility Dates of Operation (Optional) 第8部分-季节性企业的运营日期 (选填)

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(每个时段包括开始月份和结束月份)。详见Figure 12。

| Dates of Operation For Harvest 1 第一收获季运营期 | The approximate months during which the facility operates, if it operates on a seasonal basis. Select Start Month and End Month. 如果工厂按季节运营,运营的大致月份。请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. |
| 第二收获季运营期 | 如果工厂按季节运营,运营的大致月份。请选择开始月份和结束月份。 |

Figure 12

Dates of Operation

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).

| AND AND AND AND A SHOP COMPANY OF A BOARD AND AND AND AND AND AND AND AND AND AN | | | |
|--|---|---------------|---|
| Harvest 1 | | | |
| Start Month | | End Month | |
| Please Select | • | Please Select | • |
| Harvest 2 | | | |
| Start Month | | End Month | |
| Please Select | • | Please Select | * |

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

第9部分-主要产品类别-人/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).

This section is required.

根据您企业工厂的活动,您可以选择是 "Food for Human Consumption 供人食用的食品"和/或 "Food for Animal Consumption 供动物食用的食品"(如下图Figure 13)。

此部分内容必填。

| 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 – 人食用的食品;企业工厂的操作类型

This section is required.

此部分内容必填。

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,所有注册企业工厂必须完成第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.

如果您的工厂不生产、加工、包装或储存供人类食用的食品,请勾选第37项: "上述食品类别都不适用"。您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.

企业工厂操作类型为选填项。您可以选择工厂在生产/加工、包装或存储食品过程中所进行的所有类型的操作。例如,如果您选择的产品类型为 "1. alcoholic beverages(酒精饮料)",而您的工厂为 "manufacturer/processor(生产商/加工商)",则您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"选项可以让用户一次性选择所有选项或清除全部已选选项。

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

第9a部分的例子(Figure14a和Figure14b)

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

第9b部分的例子(Figure15a和Figure15b)

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

| Conducted at the Fac YPE OF ACTIVITY CONDUCT nanufacturing/processing, pa | CTED AT THE FACILITY. Check all types of operations that are performed at this facility re |
|---|--|
| Selected Product Name | Select Activity Types |
| 12. DIETARY SUPPLEMENT CATEGORIES | |
| b. Vitamins and Minerals | None selected → |

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 – 供动物食用的产品;企业工厂的操作类型

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。(见Figure15a)如果所列选项中没有适合的选项,请勾选第33项: "上述食品类别都不适用"。您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"选项可以让用户一次性选择所有选项或清除全部已选选项。

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:如果需要了解食品企业注册过程中如何使用食品类别的更多信息,请参见行业指南: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)

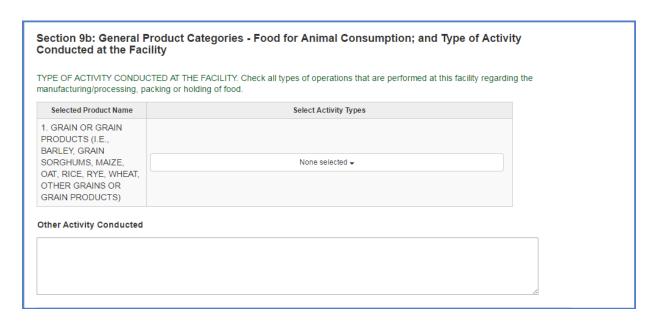
3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS

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.

此部分内容必填。

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联系信息与本表的其他部分相同,选择与之相对应的部分。否则请按要求填写信息(Figure16)。

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 理人的单位名称,如果是 个人,请填写姓名。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

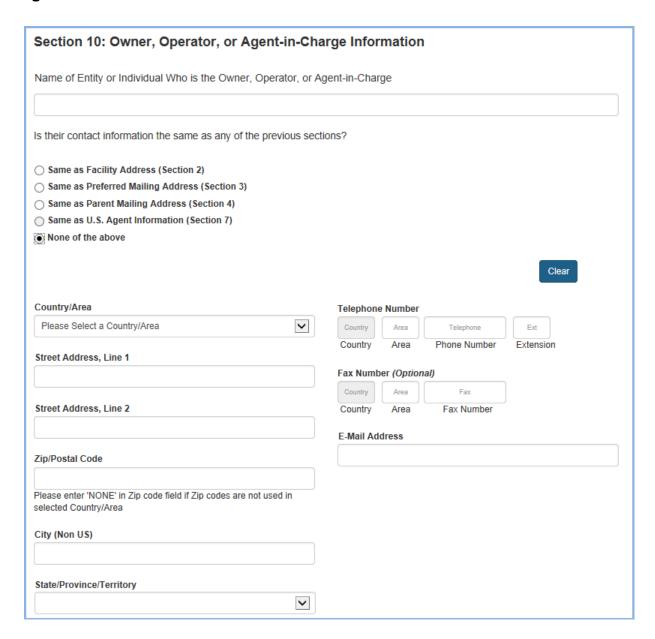
注册企业工厂的所有者、经营者或负责代理人的人员姓名或单位名称。明确所有者、经营者或负责代理人的地址信息是否与先前输入的地址信息一致。如果您选则其中一个选项,但确定信息不是您想要的,您可以手动清除并输入正确的信息。如果所有者、经营者或负责代理人的地址信息与第2部分:企业名称/地址信息中输入的地址信息相同,请选择第2部分。-或者

- 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 - 对于海外企业,如果所有者、经营者或负责代理人的地址信息与第7部分:美国代理中输入的美国代理人的地址信息相同,则选择第7部分。-或者 - 如果您需要输入新信息,请选择"None of above"。 |
|----------------------------------|--|
| 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. 注册工厂所有者、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. 注册工厂所有者、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. 注册工厂所有者、经营者或负责代理人详细地址的第2行。你可以输入房间号或门牌号。 |
| Zip /Postal Code 邮政编码 | The zip code (for domestic addresses) or postal code (for foreign addresses) for the owner, operator, or agent in charge of the facility being registered. 注册企业工厂所有者、经营者或负责代理人的国内地址或海外地址的邮政编码。 |
| City 城市 | The city in which the owner, operator, or agent in charge of the facility being registered is located 注册工厂所有者、经营者或负责代理人所在城市。 |

| State/Province/Territory 州/省/区域 | 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." 注册工厂所有者、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、省或区域,或者选择"Not applicable(不适用)"。 |
|--|---|
| Telephone Number Country 电话 – 国家区号 | For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered. 对于海外地址,注册企业工厂所有者、经营者或负责代理人电话号码的三位国家区号。 |
| Telephone Number Area 电话 – 地区代码 | The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the owner, operator, or agent in charge of the facility being registered. 美国国内地址请填写三位数字的电话地区代码,海外地址请填写城市电话代码。 |
| Telephone Number Phone Number 电话号码 | The telephone number for the owner, operator, or agent in charge of the facility being registered. 注册工厂所有者、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, 如果需要拨打分机,则填写分机号。 |
| Fax Number(optional) Country 传真 (选填) – 国家区号 | For foreign addresses, the three-digit country code for the owner, operator, or agent in charge of the facility being registered. 对于海外地址,注册企业工厂的所有者、经营者或负责代理人传真号的三位国家区号。 |
| Fax Number(optional) Area 传真(选填)– 地区代 码 | The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the telephone number of the FAX Machine of the owner, operator, or agent in charge of the facility being registered. 注册企业工厂的所有者、经营者或负责代理人是美国国内地址,则请填写三位数字的传真机电话的地区代码,如为海外地址请填写传真机电话的城市代码。 |

| Fax Number(optional) Fax Number 传真号(选填) | The FAX number of the owner, operator, or agent in charge of the facility being registered 注册工厂所有者、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 注册工厂所有者、经营者或负责代理人的电子邮件地址。 |



Section 11 – Inspection Statement

第11部分 - 检查声明

This section is required.

此部分内容必填。

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).

勾选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(Figure 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.

此部分内容必填。

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.

填写注册人和授权注册人的信息,并证明提交的信息是真实与准确的(Figure18a和 Figure18b)。一旦您完成了这部分,您将可以浏览您所填写的注册信息,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.

此表必须由企业工厂的所有者、经营者或负责代理人,或者由他们授权的个体来提交。 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,即代表企业工厂的所有者、经营者或负责代理人,或者由他们授权的个体证明所提交的信息是真实准确的,并且企业工厂已经授权注册提交人代表该工厂来提交信息。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 | | |
|--|--|--|--|
| | 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 [日本中本中 日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日本日 | | |
| | 提交此表的人员姓氏(last name/surname)和名字(first name) | | |
| 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: 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 | | |
| 勾选一项,表明谁授权您 | | | |
| 提交此注册 | 者、经营者或负责负责代理人授权的个体。 请选择: | | |
| NEXECTION . | 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(填写结束,表格已填写完 | | |
| | | | |
| | 成)-或 - | | |
| | B. Individual Authorized to Submit the Registration (Fill in address below) - If you checked box B above (Individual Authorized to 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(在下面填写地址) - 如果您勾选了 | | |
| | 上面的B选项(被授权提交注册个人),因为您不是工厂的所 | | |
| | 有者、经营者或负责代理人,则您需要确定是谁授权您来提交 | | |
| | 此注册。请选择:所有者、经营者或负责代理人(填写结束, | | |
| | 表格已填写完成。) - 或 - 填写代表工厂的所有者、经营者或 | | |
| | 负责代理人授权注册的个人姓名(在下面填写地址)。 | | |
| Individual's Name | Fill in the name of individual who authorized registration on behalf of owner, operator, or agent in charge | | |

| 代表所有者、经营者或负责代理人来进行授权注册的个人姓名 (企业代表) |
|---|
| The country/area in which the Authorizing Individual is located |
| 企业代表 (授权人) 所在国家/地区 |
| The street name and address number of the Authorizing Individual 企业代表(授权人)的地址和街道号 |
| 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。还可以填写其他具体信息例如门牌房间号。 |
| The zip code for the U.S. address of the Authorizing Individual 企业代表(授权人)在美国地址的邮编。 |
| The city in which the Authorizing Individual is located. 企业代表(授权人)所在城市。 |
| 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." 企业代表(授权人)所在州、省、或区域。如果适用,请从下拉菜单中 |
| 选择州、省或地区,或者选择"Not applicable不适用"。 |
| The Country code (for foreign addresses) of the telephone number for the Authorizing Individual. |
| 企业代表 (授权人) 电话号码的国家区号 (对海外地址) 。 |
| The three-digit area code (for domestic addresses) or city code (for foreign addresses) of the telephone number for the Authorizing Individual. 美国国内地址请填写三位数字的电话地区代码,海外地址请填写城市 |
| 电话代码。 |
| The telephone number of the Authorizing Individual. 企业代表(授权人)的电话号码。 |
| |

| Telephone Number Extension 电话-分机号 | The telephone extension, if any, dialed after the telephone number, Authorizing Individual. 如果需要拨打分机,则填写企业代表(授权人)的分机号。 |
|--|---|
| Fax Number(optional) Country 传真(选填) – 国家区号 | The Country code (for foreign addresses) of the FAX machine for the Authorizing Individual. 企业代表(授权人)传真机号的三位国家区号(海外地址)。 |
| Fax Number(optional) Area 传真(选填) – 地区代 码 | 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. 企业代表(授权人)是美国国内地址,则请填写三位数字的传真机电话的地区代码,如为海外地址请填写传真机电话的城市代码。 |
| Fax Number(optional) Fax Number 传真号(选填) | The telephone number of the Fax machine of the Authorizing Individual. 企业代表(授权人)的传真号码。 |
| E-mail Address 电子邮件 | The electronic mail address of the authorizing individual. 企业代表(授权人)的电子邮件地址。 |

Figure 18a

Section 12: Certification Statement

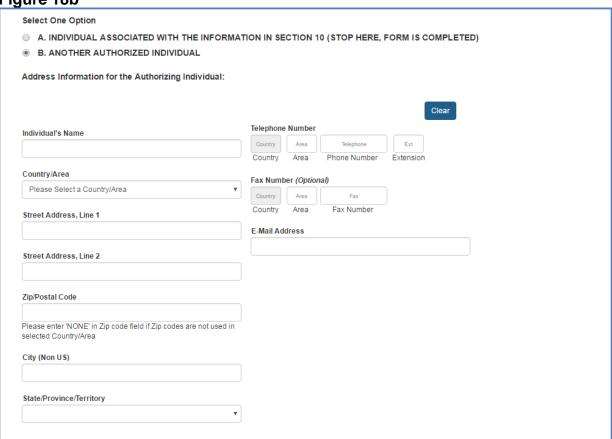
The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of 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 | 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

注册信息查验

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.

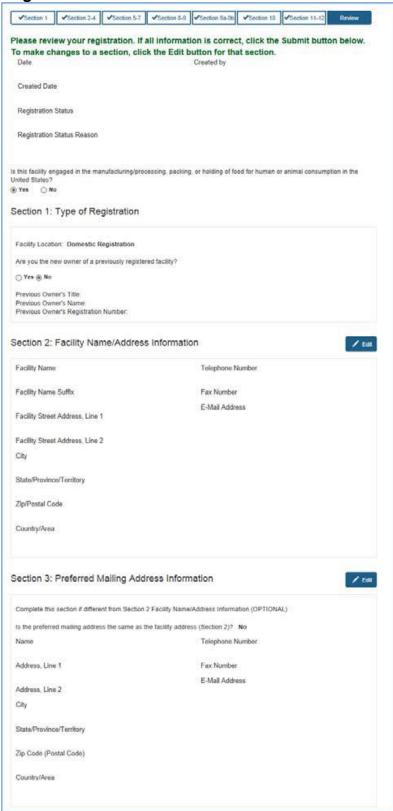
在提交前,请检查一下填写的注册信息。(Figure19,部分显示查验信息)选择 "EDIT 编辑" 选项,可以把相应的输入信息的屏幕调出,您可以进行编辑和保存修 改。

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

选择"Submit (提交)"进行注册信息的提交,或选择"Cancel (取消)"来取消提交。

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:在第1部分中的企业工厂所在地:注册类型(分为美国国内工厂或海外工厂)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,重新开始一个新的注册。



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,里面包括注册号号和PIN码(Figure 20)。请记录这些号码。

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,您可以将您的注册号和PIN告知另一账号所有人来进入系统对注册进行更新。但是请注意:如果您告知了您的注册号和PIN码,意味着此人同时也可以注销此注册。

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.

想看整个注册表格的最终版,选择"View Complete Registration(查看完整注册)"。使用屏幕最下方的按钮选项,您可以打印注册记录。或者您可以回到FFRM Main Menu(主菜单)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: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赋予该工厂的注册号码 | | |
| PIN | The Personal Identification Number for this facility's registration | | |
| | 该注册工厂的PIN码(个人识别号码) | | |
| Registration Expiration Date | The date your facility's registration will expire | | |
| 注册失效日期 | 您工厂注册失效的日期 | | |

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美国国内企业注册时,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 保存和退出 – 保存未填写完整的注册表

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2部分内容,系统将允许用户保存注册信息草稿。这将允许您保持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"Save and Exit (保存并退出)",系统将告知您,已分配了一个参考号码(Figure 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

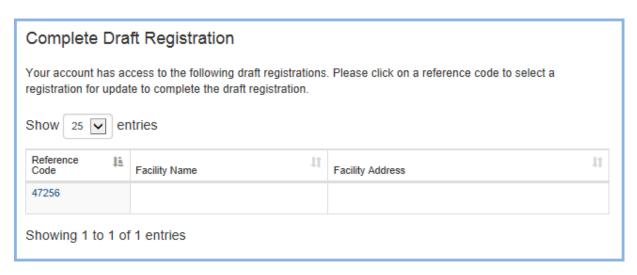
the FFRM main menu. Note: This button will only show up on the FFRM Main Menu if you have saved at least one draft registration using the save and exit option.

为了进入注册草稿,在FFRM主菜单中选择"Complete Draft Registration (完成注册草稿)"按钮选项。注:只有在您之前使用过保存并退出选项,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 "Complete Draft Registration (完成注册草稿)" 按钮选项后,系统将显示所有您可以完成的注册草稿 (Figure 22)。

Figure 22



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.

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

