

Stakeholder Webinar on Food Facility Registration (FFR), Biennial Renewal, and Unique Facility Identifiers (UFI) 8/11/2022

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Good afternoon and welcome to FDA's webinar for stakeholders to discuss food facility registration biennial renewal and obtaining an acceptable, unique facility identifier. My name is Janesia Robbs and I'm with FDA's Center for Food Safety and Applied Nutrition, Communications and Public Engagement Staff.

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Today, you will hear from Nicole Shokatz and Robert Spear from FDA's Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Field Programs Guidance. After the presentation, we will begin our questions and answers session. With that, I will now turn the webinar over to Ms. Nicole Shokatz.

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Nicole Shokatz. Good afternoon and thank you for joining us today for the FDA's Food Facility Registration and Biennial Renewal Webinar. My name is Nicole Shokatz and I am a management analyst for the Center of Food Safety and Applied Nutrition at the Data Systems Integration Branch.

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Later in the presentation, Robert Spear, our acting program manager for the Food Facility Registration Program, will be joining us for part of the presentation on unique facility identifiers. To discuss the main topic areas we will cover today. I will begin by presenting some basic information on the FDA's food facility registration program requirements.

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I will discuss who needs to register, how to register and when to register and renew. Robert As I said, we'll discuss the requirements to have a unique facility identifier and how to obtain one. Next I will cover the upcoming biennial renewal period and how to renew your registration.

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Finally, Robert and I will end with a question and answer session and address some questions that were submitted during the webinar registration process. Before we proceed, I wanted to provide some definitions of frequently used FDA acronyms and terms that you will hear throughout this presentation.

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To start FFR refers to a food facility registration. UFI is the unique facility identifier. The DUNS number is a data universal numbering system. The D&B refers to Dun and Bradstreet. When we discuss the import safety look up portal, this is the portal domestic and foreign facilities utilized to search, create, update and obtain DUNS numbers.

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UFI pending will mean that FDA has not approved the UFI at the time of the FFR submission. The registrant would have selected UFI pending with the understanding they would provide a valid accurate DUNS number within 90 days.

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A mismatched UFI will refer to the fact that the information in section two of the food facility registration and the DUNS information did not match. An invalid UFI means it has been determined that the DUNS registration is not accurate.

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And finally, FSVP, this stands for our Foreign Supplier Verification Program. In this first section of the webinar, I will cover who needs to register, basic registration requirements, what is a qualified facility?, what are registration exemptions, and who may register a food facility?

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The following guide shown here on the screen is a useful tool for answering many general registration questions you may have and is posted on our website as well. First, we need to define who is required to have a food facility registration.

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In general, the owner, operator or agent in charge of a domestic or foreign facility engaged in manufacturing or processing, packing or holding food for consumption by humans or animals in the United States is required to register with the FDA.

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There are some exemptions to this, which I will go over later in the presentation. A food facility is required to submit an initial registration to FDA prior to starting any of the manufacturing, processing, packing or holding of food.

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The term facility as it relates to this requirement includes any factory, warehouse or establishment, including a factory warehouse or establishment of an importer that manufactures, processes, packs or holds food. Food facilities that are required to register with the FDA must renew their registration every two years.

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This occurs between October 1st and December 31st of each even numbered year. The upcoming registration renewal period will begin October 1st and end December 31st of 2022. Now we will briefly discuss qualified facilities. If you are a food facility and a qualified facility under the Food Safety Modernization Act rules, you will still need to register.

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Please reference the guidance for industry to determine your status as a qualified facility. A facility that meets the definition of a qualified facility is subject to the cGMP requirements as well as the requirement the facility submit a form to FDA attesting to its status as a qualified facility.

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If you plan to attest as a qualified facility, you must still register. Unless you fall under one of the exemptions. Then you do not need to. If your facility manufactures both human and animal food, you may meet the qualified facility definition for one or both foods that you manufacture, process, pack or hold.

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You would need to submit an attestation as a qualified facility for each food for which you meet the requirement. Now we will go through the registration exemption. The exemptions to registration include the following. A foreign food facility. If food from that facility undergoes further manufacturing or processing by another facility outside of the United States. This includes packaging.

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Second is primary and secondary production farms. You can refer to the guide listed here for questions and answers on and more information on what the firm definition includes. Note that a mixed type facility in which the firm also engages in activities that fall outside of the firm definition will need to register.

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Examples of manufacturing or processing that may require a farm mix type facility to register include canning, freezing, cooking, texturizing, grinding, labeling and packaging, etc. Again, refer to the guide for additional information. Next. We have retail food establishments. We include grocery stores, convenience stores, vending machine locations, and certain farm operated businesses that sell food directly to consumers as their primary function.

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Meaning that annual food sales directly to consumers are of greater dollar value than the annual sales to other buyers. Number four is restaurants. This is defined by facilities that prepare and sell food directly to the consumers for immediate consumption.

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Number five, we have nonprofit food facilities, which are charitable entities that prepare or serve food directly to the consumer. This would include things such as central food banks, soup kitchens and nonprofit food delivery services. Fishing vessels that do not process fish but may engage in practices other than processing, such as harvesting and transporting fish, having eviscerating or freezing fish solely to prepare the fish for holding on board the vessel do not need to register.

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Number seven is facilities regulated exclusively by the US Department of Agriculture. These also do not need to register. And finally, the buildings in which a person also happens to reside a customary expectation for a private residence that is also used to manufacture, process, pack or fold food does not need to register.

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Now who may register a facility. The owner, operator or agent in charge of a facility that is required to register may authorize an individual to register the facility on its behalf.

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Nope. There is no fee for initial registration, renewing registration or updating a registration. Registration is always free. In Section two of the webinar, I will now discuss how to complete an initial registration, including the three main steps. Step one, you need to create a new FDA industry systems account, which we refer to as an FIS account.

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You can reference the user guide shown here for more information. Step two is to obtain a unique facility identifier via the DUNS number. And step three is adding a food facility registration to your account. You can reference the Food Facility Registration User Guide Step by step Instructions listed here also. And also the link to FDA industry system, the FIS system, is also shown here on the screen.

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To go through these steps a little more detail. Step one, this is what the screen will look like when you go to create a new FDA industry systems account.

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The link again is up at the top of the screen. On how to create your new account. Once you are at the FDA Industry Systems page, you will click on the log in to begin. Under new user. Click the create new account button, follow the prompts and answer all the questions to complete the creation of your account.

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If you do not already have a unique facility identifier, you will need to obtain one for each facility you plan to register. This is done by acquiring a data universal numbering system (or the DUNS number). This is done through Dun and Bradstreet.

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This will be discussed in detail in the next section of the presentation. And finally, step three is to add the food facility registration to your FIS account. Once you have your account set up and you have your UFI via DUNS number, you can now register your facilities by logging into the FDA industry systems, FIS, through the link displayed previously.

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Choose Food Facility registration from the list of available systems on the FDA account management homepage to begin. Once in the FFR system, select register a food facility from the list of options on the left. Complete all sections of the registration form as shown in the bottom picture.

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Then review all your information and you can hit submit if it looks correct. At the top of every page, a status bar will track your progress through each step. The Help link, which is the red question mark at the top of every page, will provide page specific help if needed.

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If you run into any issues or need additional help with your registration, a registration helpdesk is available on business days from 9 a.m. until 6 p.m. Eastern Time. The phone, email and website are listed here for your reference.

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I will now introduce Robert Spear, who will discuss the UFI requirements for Section three of the presentation. Hello. My name is Robert Spear, and I'm the acting food facility registration program manager for FDA. What is a unique facility identifier (UFI) and the cost of obtaining one? A UFI is location facility specific identifier and the only FDA acceptable type is a DUNS number.

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The cost is free for one facility to register and up to four changes, 90 days after the initial registration. If a company has more than one facility to register or require the registration quicker than 45 days they may be interested in the DUNS premium service.

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An accepted UFI is assigned the status of valid when a DUNS number is submitted with the FDA FFR and the system and/or personnel review the data and determine the DUNS number and FFR information match.

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A helpful link is FDA DUNS User guide at the link shown here on the slide. Beginning in the 2022 biennial renewal year, all facilities must include a unique facility identifier (known as a UFI). It's recognized as only acceptable UFI Registration submission.

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At this time the FDA recognizes the DUNS number as the only acceptable UFI for the food facility registration. UFI will be used by FDA to verify that the facility specific address associated with the UFI is the same address associated with the facility's registration.

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What is a DUNS number and how do you get one? A DUNS number is a unique nine digit numerical identifier used to identify facility at a specific location. The DUNS numbers assigned and managed by DUNS & Bradstreet known as the D&B. DUNS numbers can be obtained, updated, looked up and confirmed at D&B's website at Import Safety Lookup Portal, which is importregistration.dnb.com.

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Acquiring a DUNS number can take up to 45 days. This slide shows the actual import safety lookup portal. This is what the registered user will see when they go to the website - importregistration.dnb.com.

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Note the statement. This import safety lookup portal maybe use solely to search, identify and request update to or obtained DUNS numbers for the purpose of registering a business with the United States government.

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The portal may be used by US domestic companies and foreign companies. This is a site all FDA FFR registrants and users should utilize. Numerous things the users can do on the site is they can register to access the portal by clicking on the registered button on the website and completing the online vehicle registration form.

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After submitting the form, the system generated email will be sent to the registration email address to activate the user account. Users can manage their password by clicking on Forgot Password link on the portal's landing page. The first step to obtain an active DUNS number is to look up a facility with the Dun and Bradstreet database and if the required search field is indicated with an asterisk and click look up.

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The list of facilities, page will load with potential candidates sourced from the Dun and Bradstreet global database. I want to take the time to inform everyone, the FDA requirement for a unique facility identifier is not new

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It's been around. It has been a requirement since 2020. For the last two years, FDA has extended the flexibility of allowing users to submit a UFI pending when they're doing the food facility registration.

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However, this will end December 31st, 2022. This was announced on the FDA website on March 30th, 2021, and it's shown at the link shown on this slide. Since 2020 domestic and foreign facilities that manufacture, process, pack or hold foods for human or animal food consumption in the United States are required to submit a unique facility identifier and or food facility registration with the U.S. Food and Drug Administration.

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As previously mentioned in this presentation, FDA has previously allowed facilities more time to obtain and submit the unique facility identifier with the registration submission. This requirement began in the 2020 biennial registration renewal period.

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FDA extended the time period to obtain and submit an UFI until December 31st, 2022. The requirements to include an UFI began during past registration and it was implemented in accordance with the 2016 rule implementing the food facility registration provisions in the Federal Food, Drug and Cosmetic Act.

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The requirement applies to both new facilities registering for the first time and those submitting a registration renewal. Common mismatch issues with DUNS numbers. Do not use the agent or shipper information. Always use the facility physical location. Do not use the headquarters location.

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Each physical location needs a DUNS number. Another error is in one database the corporate address may be listed as facility. However, in the DUNS number, they may list the manufacturing location or vice versa. Remember, both these databases need to match exactly.

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This is a slide we put together. The UFI field has been added section 2-Facility Name/Address Information of Form FDA 3537, Food Facility Registration which is part of the electronic form that users use when they submit their registration.

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It is imperative that the FDA FFR Section two and the DUNS number information match exactly. Any information in the highlighted section that will cause a mismatch. The slide provides hypothetical information that would cause data mismatch referred to as a UFI mismatch.

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Please note the submitted information is first vetted for screen by artificial intelligence, which means abbreviated shortened spellings, etc. will cause mismatches. Remember to submit the legal name, physical address, city and country, and it should be spelled out in their entirety.

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Please take a look at some of the examples on the slide. For example, in the food facility registration section 2, ABC Manufacturing was submitted. However, on the DUNS number ABC LLC was submitted, this would cause a mismatch. Other common mismatches are, for example, if someone spelled off the word Street – S-T-R-E-E-T. However they abbreviated in the other database “St.”

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For example, “St.” could mean Saint, as in Saint Louis. DC could mean the District of Columbia. These are all mismatches. So all of these have to match exactly in both databases. So far, in 2022, FDA sent out three email letter notifications, one in May, one in June and one in July, informing noncompliance registrants their FFRs possess three possible noncompliance statuses of “UFI Pending”, “Mismatched UFI” or “Invalid UFI”.

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All three of these statuses indicate the FFR and UFI are not in compliance with FDA FFR requirements. Mismatched UFI has already been discussed.

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“UFI pending” status is when the registrant created a FFR and selected “pending” for the UFI submission with the understanding a valid, accurate UFI (DUNS number) would be submitted within 90 days. What potentially happens if facilities fail to update the registration with an accurate, valid DUNS number within 90 days?

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This noncompliance can result in cancellation of the registration for failure to renew in accordance with 21 CFR 1.230(b). Ultimately, what will happen if FDA does not extend the December 31, 2022 deadline? The above mentioned FFRs and those that are not renewed will be cancelled in January 2023.

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Once canceled, the registrar will not possess a valid, accurate FFR. This meant that imported food shipments will be consumed in the United States. When the old, canceled FFRs are submitted in electronic database, they will be rejected and the entries submitted and the entry will not be processed.

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If an entry is submitted without a valid, accurate FFR, the shipment will be held at the port of entry until a valid FFR is submitted. If a valid, accurate FFR is not received in a timely manner, the shipment will be reexport.

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Always remember the DUNS numbers, three of the four changes in the 90 days of registration. As you can see on the slide, the D&B’s phone numbers 866-705-5711. Any questions related to the DUNS number can be sent to the email the importsafety@DNB.com.

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And as mentioned earlier, all questions related to registering, updating or verifying a DUNS number could be set to importregistration.dnb.com. And as mentioned earlier, any questions related to the food facility registration can be directed to the FURLS helpdesk at furls@FDA.gov.

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And a toll free number of 1-800-216-7331. And for international callers, it is 240-247-8804. Thank you, Robert. In this next section of the webinar, I will be covering how to update your current registration, the difference between initial registration versus the biennial renewal.

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When the biennial food facility registration renewal period will be. And finally, I will briefly cover the steps to renew your registration. Also remember you can refer to the Food Facility Registration User Guide. Biennial Registration Renewal for complete instructions and renewal steps.

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Please note if registration is not renewed by 11:59 p.m. on December 31st, 2022, the registration is considered expired and will be removed from your account. Updating your registration for this part, you want to ask yourself, has any of your information changed since you last registered or renewed?

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For example, phone numbers, preferred mailing address, parent company information, products that you manufacture, facility name or person in charge information, etc.. If yes, you need to update your information at the FDA industry system or FIS page. Once you are logged in to the FIS and into your account, you'll choose the food facility registration system, and then you will choose the update facility registration option from the FFR main menu.

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Select the registration account you want to update and which sections you need to update. Review the updates and select submit. Refer to this guide on updating registration for full instructions on updating listed here on the screen.

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Please note, though, if you need to change the physical location of the facility information, you must create a brand new registration after you cancel the existing registration through the Cancel Registration Main Menu Option. Also note. Updating registration is not the same as renewing your registration.

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The difference between initial registration versus biennial renewal, is that you only need to register your facility with FDA once referred to as initial registration. Once the registration is submitted, it is assigned an 11 digit registration number and a PIN versus biennial renewals, which occurs every two years on even numbered years, during the biennial renewal period.

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The facility keeps the existing registration numbers that they were given during initial registration and then renewing your registration, it ensures that the registration remains valid and in compliance for the next two years. Beginning on October 1st, 2022, you can log into the food facility registration system at the FIS, FDA Industry System Account Management page listed here and use your PIN to access the renewal portal.

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If you've forgotten your PIN. Follow the steps in this user guide to retrieve. You are now ready to renew your registration. Once you are logged into the FDA industry system to the Food Facility Registration FFR tab and then select the biennial Registration Renewal 2022 option from the FFA menu listed on the left.

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The system will then display a list of all your registrations that are available or due for renewal. To complete the renewal process, select the registration number, hyperlink within the table and the system will display the registration review screen.

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FDA does have an abbreviated biennial registration renewal process for a facility that has not had any changes to its registration information since the previous registration or registration renewal period. Please read the instructional text at the top of this screen carefully.

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Only sections of the registration with an edit button displayed next to it may be updated during the biennial registration renewal process. Once you have reviewed the information and made any other updates as necessary, submit your changes to complete the renewal process.

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Remember, you can reference the Food Facility Registration User Guide, Biennial registration renewal for further instructions. And it's shown here on the slide. To conclude this presentation, please remember that registering your food facility and renewing each biennial renewal period is required, and there are consequences if you do not register on your facility as required.

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Food Facility registration helps FDA to determine the location and source of an outbreak of foodborne illness or a potential bioterrorism incident. And ensures we can quickly notify facilities that may be affected by a related recall event or another safety food safety incident.

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If you do not renew your registration on time or if the information is incorrect or inaccurate, FDA may cancel your registration and you will have to submit a new registration for your facility prior to resuming your facility's activities.

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Failure to register your facility, renew your registration, update required elements or cancel registration in accordance with Section 415 of the FD&C Act and Applicable Regulations is a prohibited act under the FD&C Act. The federal government can bring a civil action against the person who commits the prohibited act, or it can bring a criminal action to prosecute a person who is responsible for the commission of a prohibited act or both.

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FDA will consider a registration for a food facility to be expired if the registration is not renewed. Now, Robert and I will answer some of the questions that were submitted during the registration process.

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Thank you, Nicole and Robert. We will now start our question and answer portion of the webinar. We received several questions during the webinar registration process. We will now cover our most commonly asked questions, starting with questions on the registration process.

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Our first question, will go to Nicole. A manufacturing facility is currently being constructed. At what point in the process should you complete registration for a new company? Food facilities must be registered before operations begin, including manufacturing/ processing, packing, or holding food for consumption by humans or animals in the United States.

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This next set of questions refers to alcohol manufacturer registration requirements. Are alcoholic beverages with more than 15% alcohol content manufacturers required to register? Second question, Being a winery, are we eligible for Exempt status? and. Question number three. I own a very small micro brewery. I am registered but do I need to be?

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Yes. For food facility registration purposes. FDA considers alcoholic beverages of all proof or type or percentages as food. Note The winery may qualify as a retail food facility if the retail onsite sales exceed all other types of sales.

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Are importers without warehouse space required to be registered.? No, only if you are engaged in manufacturing/processing, packing, or holding food for consumption by humans or animals in the United States are you required to register. Does the start-up company who doesn't have a manufacturing facility and produces their product at co-manufacturer's facility and distributes it through the supply chain partners need to have FDA registration?

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Yes, you must register with the facility address of wherever you are currently manufacturing or processing. Use the co-manufacturer's physical address along with your contact and other information to register.

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For Seasonal facility that operates only during the season at each facility, are they required to register each facility separately or use the same registration with both locations. You must register each facility location separately. Each location needs its own food facility registration.

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Does FDA issue registration certificates? FDA does not honor or issue a certificate as proof of registration. FDA considers a copy of a valid registration to be the proof of a registration. What if a company does its animal food manufacturing entirely through contract manufacturer, organization or CMOs, although its name appears as a guarantor on the feed label? Does that company need a separate registration or only the various HMOs who are actually performing the production steps?

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If the company that is the guarantor on the feed label does not manufacture, process, pack or hold their animal food, then the company does not have to register as a food facility. The CMOs that manufacture, process, pack or hold the company's animal food products, would need to register as a food facility.

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Can I use the same FFR if the factory manufacturing human food and pet food at the same place or location?

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Yes, you only have to complete one food facility register for the same place or location that manufactures, process, packs, or holds the human and animal food. In Section 9: General Product Categories within the food facility registration, you can select "Food For Human Consumption" and "Food For Animal Consumption". You can check both of these boxes and fill in what your facility's activities are for both human and animal food. You can check both of these boxes and fill in what your facility's activities are for both human and animal food.

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We currently use a third-party registration service and would like to register on our own. What is the process for this? Do we have to start from scratch? We do. US FDA renewal through a consultant. Can we do it directly with our help from that consulting company?

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Yes. Remember registration is free and you can register yourself through the FDA Industry Systems website, as we discussed in the webinar. You do not have to go through a consultant to register your facility.

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We understand the FFR number is confidential, but many of our handlers were previously not aware of their FEI numbers that we're using now for facility registration with China. Who uses FEI numbers in the USA?

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FEI is an acronym which stands for **FDA Establishment Identifier**. It is also known as the Firm or Facility Establishment Identifier. The FEI number is a unique identifier assigned by the FDA to identify all firms associated with FDA regulated products. Not just food facilities. The FEI is not the same as the Food Facility Registration number or the UFI. It is an identified used internally by the FDA.

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Can you please clarify whether packinghouses that meet the farm definition and the preventive controls for a human food rule should register or reregister as a food facility?

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Yes. Again, reference the guidance on questions and answers for food facility registration that goes into detail on farms and the farm definition. But to answer this question about packing houses, if the packinghouse's manufacturing and processing consists only of things such as:

- Drying or dehydrating raw agricultural commodities to create a distinct commodity for example such as drying/dehydrating grapes to produce raisins without additional manufacturing or processing such as slicing then that is except.
- Treatment to manipulate the ripening of raw agricultural commodities such as by produce with ethylene gas, and packaging and labeling treated raw agricultural commodities.
- And third, if you are packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

In these cases the packing house does not need register.

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I have a central kitchen or a firm that prepares food at a central location (where there are no sales to end consumer happen at that location) and then provide that food to my own retail locations or restaurants. Do I have to register?

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Yes, under 21 CFR 1.226(sub section D), restaurants are not required to register. However, central kitchens that do not sell the food, they prepare directly to consumers for immediate consumption are not "restaurants." Thus, they are not exempt, as restaurants, from registration. So the central kitchen would have to register.

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Are food sites obligated to share the registration number with customers or other parties? Section 415(a)(5) of the FD&C Act provides that certain registration-related information, including the registration number, is not subject to disclosure under Freedom of Information Act.

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However, this does not prevent a facility itself from disclosing such information. In fact, for imports, a facility will likely need to provide its registration number to any downstream commercial entity who will

be submitting prior notice for a food manufacture. The FD&C Act does not prevent a foreign facility from entering into an agreement with its customers to limit the circumstances in which the facility's registration number may be disclosed to third parties.

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If we are leasing a section of an offsite warehouse, who is responsible for our registration and what if there are multiple industries renting different sections of the same warehouse?

00:39:06:05 - 00:39:22:20

So again, the owner, operator, or agent in charge is a person who has an ownership interest in, or management authority of a facility or a portion of a facility. For example, a lessee of a part of a public warehouse that manufactures, processes, packages or holds food, must register.

00:39:23:14 - 00:39:48:18

Is food facility registration the same as bioterrorism registration. Yes, registration is an FDA requirement per the Public Health Security and Bioterrorism and Response Act of 2002.

00:39:51:10 - 00:40:15:01

Is there a need for manufacturers producing cannabis or hemp products to register? Will there be a need in the foreseeable future? Currently marijuana, cannabis or cannabis edibles are not regulated by the U.S. Food and Drug Administration, so manufacturers are not required to register for a food facility registration at this time.

00:40:18:12 - 00:40:44:08

Please discuss registration requirements pertaining to food contact materials and packaging article manufacturers. Okay, the definition of food in 21 CFR 1.227, for the purposes of food facility registration excludes food contact substances as defined in section 409, subsection H, subsection six of the FD&C Act.

00:40:45:04 - 00:41:17:19

Consequently, a facility that manufactures or processes, packs or holds food contact substances, including food packaging or bottled water containers or closures, is not required to register. How and when must a facility canceled its registration? The owner, operator or agent in charge of that facility or an individual authorized by one of them must cancel the registration within 60 calendar days of the reason for the cancelation.

00:41:17:19 - 00:41:37:28

For example, if a facility goes out of business or comes under new ownership, the owner, operator or agent in charge must cancel the registration. You can submit the cancelation electronically at <https://www.fda.gov/furls>.

00:41:41:22 - 00:42:03:03

The next set of questions refer to renewal registration. Do I need to re-attest as a qualified facility during the biennial renewal period? Yes, the facility must re-attest as a qualified facility after the food facility registration has been renewed.

00:42:03:21 - 00:42:30:00

Otherwise, after December 31st, 2022, any previous attestation status is no longer applied to your registration, even if you have renewed your registration. I have recently taken over a position that was vacated. I need to renew the FDA registration for four facilities this year, but I do not have the FDA log in that was previously used by the previous employee.

00:42:30:00 - 00:42:51:08

And I'm interested in the best way to renew registration and/or update the login credentials for the facility so that I can renew. In this case, please contact the FURLS support helpdesk. I had provided this slide during the webinar with the phone number and the email and the web address.

00:42:52:13 - 00:43:11:01

The email is furlssupport@fda.hhs.gov. You can provide them with a statement on company letterhead signed by the most responsible person of the firm explaining the details of the situation, the locations and the FFR numbers and any other pertinent information to include the name of previous individual that registered the firm. And they would be able to help you.

00:43:11:05 - 00:43:30:28

Can I renew early? No. Early renewal submissions are not accepted.

00:43:31:08 - 00:43:48:27

The renewal period begins October 1st, 2022 and will end December 31st, 2022. Thank you, Nicole, for answering those questions. Our next set of questions refer to the UFI and DUNS number. We'll now turn it over to Robert Spear to answer those.

00:43:51:16 - 00:44:11:21

Let's start with our first question. Will the new code UFI replace the registration number? Is it necessary to place the UFI on the export invoice, or is this code confidential? The answer is no. Remember, the UFI number will not replace the FFR number.

00:44:12:09 - 00:44:31:19

Matter of fact the UFI number to be submitted in the FFR registration and FDA does not require that UFI be placed on an export invoice. How does the FDA plan to address, duplicate or multiple DUNS numbers that have been issued for a single facility in the past by Dun and Bradstreet?

00:44:32:01 - 00:44:54:17

This appears to be creating issues when comparing the UFI listed in Food Facility Registrations to the D&B database. Remember DUNS and Bradstreet (known as D&B) performs a vetting process that

identifies duplicates. Multiple DUNS numbers for one single facility often happens when more than one industry representatives requested a DUNS number for the same facility.

00:44:54:17 - 00:45:17:14

If a facility has a duplicate or multiple DUNS numbers, they should, number one, check in their FFR section two submit the DUNS that is the exact match to their FFR as mentioned in the presentation. Number two, contact D&B at ImportSafetySupport@DNB.com with the current and complete facility name, address, list of the multiple/duplicate DUNS, and the UFI that was submitted with their FFR.

00:45:17:26 - 00:45:32:08

Note, that it is critical that industry use the official D&B Import Safety Lookup Portal at <https://importregistration.dnb.com> to obtain or verify DUNS numbers as 3rd parties may not have the most up to date information.

00:45:34:19 - 00:45:54:18

Another question about whether a firm that has changed ownership keeps the same DUNS number or needs to get a new DUNS number. If a facility comes under new ownership, the former owner must cancel the old registration in accordance with 21 CFR 1.235.

00:45:55:01 - 00:46:17:23

And the new owner must submit a new registration for the facility as specified in 21 CFR 1.1231. Also see 21 CFR 1.234 Subsection B. If a facility cancels its registration due to a change in ownership, the new owner, operator or agent in charge must provide the appropriate UFI when registering a facility under the new ownership as per 21 CFR 1.232.

00:46:17:24 - 00:46:36:18

If only the ownership changed, and the facility information is still the same it is most likely the same DUNS is appropriate as the DUNS Number is constant—it stays with a business throughout the lifecycle. Could you provide some clarity regarding DUNS number versus Sam UFI?

00:46:36:18 - 00:46:56:00

Are DUNS numbers still valid? Are SAM numbers only for doing direct business with the Government? FDA recognizes the DUNS number as the only unique facility identifier (UFI) for registration or renewal in the Food Facility Registration Module (known as the FFRM).

00:46:56:18 - 00:47:14:07

The SAM number is a Unique Entity Identifier that is used only for doing business with the government. So remember, creating or renewing a Food Facility Registration is not considered doing business with the government. Is the unique facility identifier the same as a unique entity identifier?

00:47:16:09 - 00:47:32:08

No, they are not the same. The unique facility identifier known as the UFI is used when you submit your food facility registration or renewal for the food facility registration module. FDA currently recognizes that Dun and Bradstreet DUNS number as the only acceptable UFI for a food facility registration.

00:47:35:14 - 00:47:55:12

If you have a warehouse building that is separate from a manufacturing facility, but does all the shipping for it, does it have to be a separate DUNS number? Yes. Each facility is engaged in manufacturing, processing, packing or holding of food for human or animal consumption in the United States, must register with FDA, unless you have exemption under 21 CFR 1.226 from the requirement to register.

00:47:55:26 - 00:48:11:10

Each food facility registration will have its own unique facility identifier UFI/DUNS number. The UFI must be an exact match to the firm's legal name and physical address as submitted in Section 2 of the Food Facility registration. Note: "Facility" is defined to include structures under one ownership at one general physical location (21 CFR 1.227).

00:48:11:10 - 00:48:36:01

Why does FDA send a notice to companies indicating they have incorrect you if I if the registration information is the same as the DUNS account information.

00:48:38:09 - 00:48:51:17

FDA sends emails to firms that had a pending, invalid or mismatch UFI. Remember common reason for this status is that a UFI was not entered or the information in the FFR, Section 2 is not an exact match to the DUNS information.

00:48:55:09 - 00:49:18:07

If "Inc." is part of the facility name (and also the name associated with the DUNS number), does "Incorporated" need to be selected in the "Suffix" section? No. The facility name suffix is not a field matched with DUNS. The matched information is on slide 20 and is the information with the rectangles around them.

00:49:21:27 - 00:49:45:10

Will FDA be creating a publicly accessible database of registered food facilities similar to the drug and device establishments? No. Section 415 Subsection A, 5 provides that the list of registered facilities and registration documents, including information provided in this document that submitted on 21 CFR Part one Subpart H are not subject to public disclosure under Freedom of Information Act, known as FOIA (5 U.S.C. 552).

00:49:45:10 - 00:50:02:26

In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person is not subject to disclosure as mentioned under 5 U.S.C. 552. You can refer to Questions and Answers Regarding Food Facility Registration (Seventh Edition), which is on the FDA public website.

00:50:03:10 - 00:50:22:18

What are common errors FDA has seen when validating UFI DUNS numbers in food facility registrations?

00:50:24:21 - 00:50:41:06

Providing the US Agent's DUNS number, providing the Headquarters/office location DUN's number; and FFR Section 2 are not an exact matches as mentioned in the presentation. Such things as abbreviated St. That could mean Street, could mean Station, Saint, Strasse

00:50:41:19 - 00:51:01:11

Remember section F, part section two in the DUNS number information should the match exactly. Do not abbreviate them. Do not shorten the spelling. Is there an expiry date for the DUNS number? Why would an initial DUNS number become not valid?

00:51:03:10 - 00:51:20:19

DUNS Numbers do not expire, however, FDA representatives perform risk-based vetting, which may reveal the submitted information is inaccurate, incorrect or invalid when section two of the FFR and the DUNS number is compared. At that point, the FFR is given the status of mismatched or invalid.

00:51:23:24 - 00:51:44:11

Only some of our facilities have DUNS numbers. If a facility has multiple buildings, each with a separate address does every building need to be registered? Yes, each facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States, must register with FDA, unless you have an exemption under 21 CFR 1.226 from the requirement to register.

00:51:44:11 - 00:52:00:15

"Facility" is defined to include structures under one ownership at one general physical location (as per 21 CFR 1.227). If you need assistance in determining if multiple buildings are one general physical location, please contact cfsanfoodfacilityregistration@fda.hhs.gov. And they will answer your questions.

00:52:01:02 - 00:52:38:16

Our office and factory are right next to each other with almost the same address, just the numbers have one different digit (like 881 and 883). Office has a DUNS number in the database but factory does not. It doesn't seem to make any sense to create a new DUNS number specifically for factory though. What would FDA recommend for a situation like this?

00:52:39:09 - 00:53:01:14

Each Food facility Registration or the facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States which is listed under Section 2 – Facility Name and Address Information.

00:53:02:01 - 00:53:15:03

Remember the DUNS is a UFI for the facility being registered; therefore, yes the factory needs its own DUNS number. The office address may be listed under Section 3 of the Food Facility Registration– Optional: Preferred Mailing Address Information.

00:53:19:02 - 00:53:40:04

There appears to be UFI validation issues when a facility has special foreign characters in the corporate name or address in their DUNS listing when FURLS does not allow these characters during registration. Can you provide some guidance?

00:53:40:17 - 00:53:53:16

FURLS does not recognize any special characters so please ensure the FFR section two and the DUNS number match exactly to include the legal name, legal physical address, city and country. All those should be spelled out so they match exactly. The example was discussed in the webinar and is located on the Food Facility Registration User Guide: Biennial Registration Renewal.

00:53:53:16 - 00:54:18:08

We are having issues with DUNS numbers. There seems to be a disconnect with DUNS and the FDA. They state that we only need one number for our company, but the FDA requires a unique number for each FDA registered location. DUNS is not prepared for the workload to get all of these issued, and the process is complicated and time consuming. Are you addressing this with D&B?

00:54:18:29 - 00:54:35:22

Yes, FDA is addressing this and we have meetings every two weeks with the Dun and Bradstreet representative.

00:54:36:09 - 00:54:57:10

But remember, each distinct, specific facility located at distinct, specific locations require unique individual DUNS numbers and FFRs. Common errors were discussed during the webinar and the free public accessible website shows common errors at Food Facility Registration User Guide: Biennial Registration Renewal.

00:54:57:19 - 00:55:11:27

Note that it is important that you contact the D&B Import Safety Lookup Portal helpdesk directly at ImportSafetySupport@DNB.com. Remember other D&B departments do not have the specialized training and dedicated staff to assist with FDA Food facility registration requirements.

00:55:14:17 - 00:55:31:19

We recently purchased a facility and used the UFI that was on their previous registration, we received notice that the UFI was not recognized. We tried to obtain a DUNS number and was told that DUNS was no longer doing that and to reach out to FDA. We did so over 2 weeks ago and have receive no response.

00:55:32:10 - 00:55:52:29

It is important that you contact the D&B Import Safety Lookup Portal helpdesk directly at ImportSafetySupport@DNB.com as other departments do not have the specialized trained and dedicated staff to assist with FDA Food Facility Registration requirements. Also, you may find step by step directions in the quick user guide at <https://importregistration.dnb.com/QUICK USER GUIDE Import Safety Portal.pdf> to obtain or verify your DUNS number.

00:55:53:21 - 00:56:30:04

This concludes today's webinar. As we noted at the beginning of this webinar, we received many questions during the registration process as we could not get to all of the questions that were submitted. We will follow up with more Q&A and add it to our [webinar] registration page on FDA's website. Thank you and have a great rest of the day.