FDA GUIDANCE IN PLAIN ENGLISH

This is the response to the help request from FDA:

With certain exemptions, any establishment engaged in the manufacture, repacking, relabeling, or salvaging of a drug product for commercial distribution is required to register with FDA. Food facility registration is different from drug registration.

Any SPL authoring software may be used to create registration and listing SPL files. The FDA website offer two SPL authoring tools -- CDER Direct and Xforms. One of the simplest ways to submit SPLs is through the use of CDER Direct, a free tool from the FDA. You can create an account at https://direct.fda.gov *(see attached for instructions)*. After you sign up for an account and it is confirmed, you can begin creating and sending SPL submissions to the FDA.

1. Create a DUNS number if you do not have one. Our recommendation is to follow this sequence of steps: https://www.dnb.com/duns-number/get-a-duns.html

2. Create a CDERDirect account – **FDA Slide Set #1 Https://direct.fda.gov**

3. Register the establishment if you are a manufacturer or performing manufacturing processes **FDA Slide Set #2** Electronic Code of Federal Regulations Link - https://www.ecfr.gov/cgi-bin/text-idx?SID=db44a05bff49df1b148f18db961172bd&mc=true&node=pt21.4.207&rgn=div5

4. Request a labeler code (Labeler codes are only used for generating National Drug Code (NDC) numbers for drugs) **FDA Slide Set #3**

5. List the product **FDA Slide Set #4**

Here is a link to our instructions page. On the page you will find guidance on how to register your establishment, request a labeler code and list a drug product. The attachments will help you if you choose to use CDERDirect.

https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

Let us know if you need any additional assistance.

Regards,
eDRLS Staff (ph)

1. We already had a DUNS number, and we did not have to complete this step.

2. Create a CDERDirect account **FDA Slide Set #1**

    1. Under QUICK LINKS on the right, click on 'Create Account'

    2. under 'Brief Description" we wrote: new commercial hand sanitizer production

    3. filled out rest of form

    4. on FORM ACCESS at the bottom, checked 'ESTABLISHMENT REGISTRATION'

    5. hit 'SUBMIT'

    6. It took about 1 hour to get a confirmation email. In the email, we clicked the link to activate the account, and filled out the remaining parts of the form to activate the account.

3. Register the establishment **FDA Slide Set #2**

    1. Select 'CREATE NEW', then 'CREATE NEW ESTABLISHMENT REGISTRATION USING BLANK FORM'

    2. Fill out the forms which are pretty straightforward, through Registrant Details. At the bottom right, click 'ADD ESTABLISHMENT'

    3. Fill out Establishment Details form, contacts form, through importers, etc. When you get to BUSINESS OPERATIONS, select "MANUFACTURE" - "MANUFACTURES HUMAN OTC DRUG PRODUCTS UNDER A MONOGRAPH"

    4. FDA recommends saving a draft before clicking "SUBMIT SPL"

    5. Wait for approval of the submission.

4. Request an NDC labeler code **FDA Slide Set #3**

    1. Click - "Create new NDC Labeler Code request using a blank form"

    2. Fill in the obvious boxes and contact information. For Business operation, put "MANUFACTURE" and "MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH" as the qualifier.

    3. Wait for email that labeler code has been assigned. The email will have your Labeler code, a five digit number.

    4. The go into NDC Labeler code entry and CREATE A NEW VERSION (version 2). Put the Labeler code in the appropriate box. Hit "SAVE AND VALIDATE". After it is approved, SUBMIT SPL.

5. Here's where it gets fun. List the product **FDA Slide Set #4**

    1. You will be creating a single product type, and perhaps multiple sizes of packaging for that product type (eg. Hand sanitizer). Most boxes are self-explanatory, the ones that

aren't are here:

- Document Type: HUMAN OTC DRUG LABEL
- Establishment, Business Operation: MANUFACTURE
- Establishment, PRODUCT NDC (See step 3 below)

2. Create a new Product Type. You will create a New Product Listing for the CLASS of product (i.e. Hand sanitizer). You will add different package types later (multiple sizes).

3. NDC Product Code = XXXXX-YYYY

where XXXXX is assigned to you by email

and YYYY is a sequence number you pick (eg 0001) for the product.

4. Proprietary and Non-proprietary name: Anything you like

5. Dosage Form: LIQUID

6. Route of Administration: TOPICAL

7. Marketing Category: OTC monograph not final

8. Application Number / Regulatory Citation: part333A

9. Add your ingredients one by one. Active Ingredient:

Ethanol UNII no. 3K9958V90M, Denominator = package mL, Ingredient strength=0.8*total mL

10. Inactive Ingredients:

Glycerol UNII no. 3L7GRZ604E, Denominator = package mL, Ingredient strength=0.0145*total mL

Peroxide UNII no. BBX060AN9V, Denominator = package mL, Ingredient strength=0.00125*total mL

Water UNII no. 059QT0KKO0R, Denominator = package mL, Ingredient strength=remaining mL

11. Do not fill in Product Image, nor Characteristics

12. Packaging... you will create one for each size you offer. We did 6oz, 25oz, and 64oz, so three entries. You can clone them from the first one you do.

13. For each PACKAGING, put Quantity in mL and select mL as Unit of Measure. So, for 6oz, it's "177" and "mL."

14. Package Type, presumably, "BOTTLE, PLASTIC" or whatever.

15. Combination Product Type: "Type 0: Not a Combination Product"

16. PACKAGE NDC = XXXXX-YYYY-Z

As above but with Z as a sequence number that you choose for the package type

17. Go back to the top level of the product. Hit "RETURN" until you're at the top of the

product. Hit "CONTENT OF LABELING" button (top left).

18. The following sections must be added in this section. <u>You will have to do them one by one. This is tedious.</u>

- Active Ingredients Section
- Do Not Use Section
- Keep out of reach Section
- Purpose Section
- Stop Use Section
- When Using Section
- Other Safety Information Section
- Warnings & Precautions Section
- Directions Section
- Inactive Ingredients Section
- Principal display panel section
- Dosage and administration section
- Warning Section (different from Warnings & Precautions above!)
- Indications & Usage section

For each of these sections, and you can't skip any of them, you must copy the information (cut and paste) from your label in text into the "Contents" box. For the Active Ingredients section, upload a picture of your rear "Drug Facts" label and add it as an image into the "Contents" box after the text. For the Principal display panel section, upload a picture of your front label and add it as an image into the "Contents" box after the text.

19. Hit SAVE AND VALIDATE. They may bounce it back, and if so, email the helpdesk as they've been pretty helpful and responsive (cderdirect@fda.hhs.gov). If you get approved, you're good to SUBMIT SPL and you're in like Flynn. You have now registered a product with the FDA! Congrats.