How to obtain a Small Business Designation (SBD) with the FDA

a.k.a. How to save ~16 grand on your 510(k) fee

FDA Small Business Program

If you're a small business or start-up planning a submission with the FDA, you should *DEFINITELY* know about FDA's Small Business Program.

CDRH's Small Business Program determines whether a business is qualified and certified as a "small business" and eligible for a reduced fee for some types of CDRH submissions that require a user fee.

Gross receipts & sales < $100 million for the most recent tax year

Great, but how much is the discount?

*** For FY2024**

	Standard Fee*	Small Business Fee*	Discount
513(g)	$6,528	$3,264	$3,264 (50% off)
510(k)	$21,760	$5,440	$16,320 (75% off)
De Novo	$145,068	$36,267	$108801 (75% off)
PMA	$483,560	$120,890	$362670 (75% off)
Annual Establishment Registration	$7,653	No discount for small businesses ☹👎	

But at least the above savings can help you pay for your annual establishment registration!

I need this. When should I apply?

It may take up to 2 months so apply at least 60 days before you need it

When should I renew?

The small business status expires on September 30 of the fiscal year in which it is granted

A new request must be submitted and approved each fiscal year to qualify as a small business

Each FDA fiscal year starts October 1st

If you can, apply as early as August 1st

Example

A business that obtained small business status on Nov. 7, 2022 will have this status through Sep. 30, 2023.

Submitting a request in Sep. 2023 may not result in a response prior to Oct. 1. If you do receive the response in Sep. 2023, you will not be able to use the small business decision number after the start of the new fiscal year (Oct. 1, 2023).

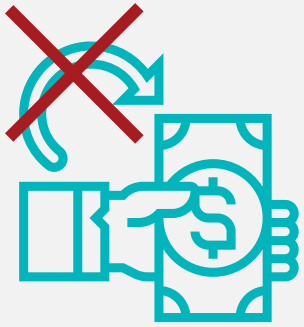
Important

≠

Obtaining a Small Business status is *NOT* the same thing as doing your Establishment Registration, which is done in FURLS once commercialization has started and then each year between Oct. 1 and Dec. 31.

Submission fees are paid through the User Fee System (MDUFA)

Important



If you did not get your Small Business Designation prior to paying submission fees, FDA will not refund you.

Small business reduced fee for submission does *NOT* apply if you're using a 3rd party reviewer (only works if submitting / paying directly to FDA)

Let’s get started.

Equipment needed: your favorite bottle (full)

First Things First

Go to →
https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp

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. Please note that:

(i) The user is accessing a U.S. Government information system,

(ii) That system usage may be monitored, recorded, and subject to audit,

(iii) That unauthorized use of the system is prohibited and subject to criminal and civil penalties,

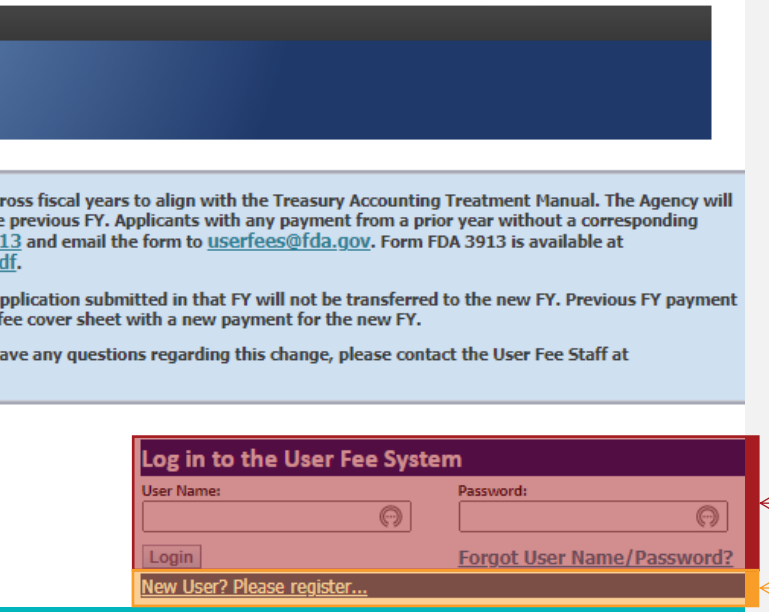
(iv) That use of the system indicates consent to monitoring and recording, and

(v) Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

◉ I understand

Need Help? Click Here For Assistance.

First Things First



Have you paid the user fee before (i.e., do you have a User Fee System Account)?

Yes

Log in to retrieve your Organization ID Number

Skip to page 17

No

Create your User Fee System Account

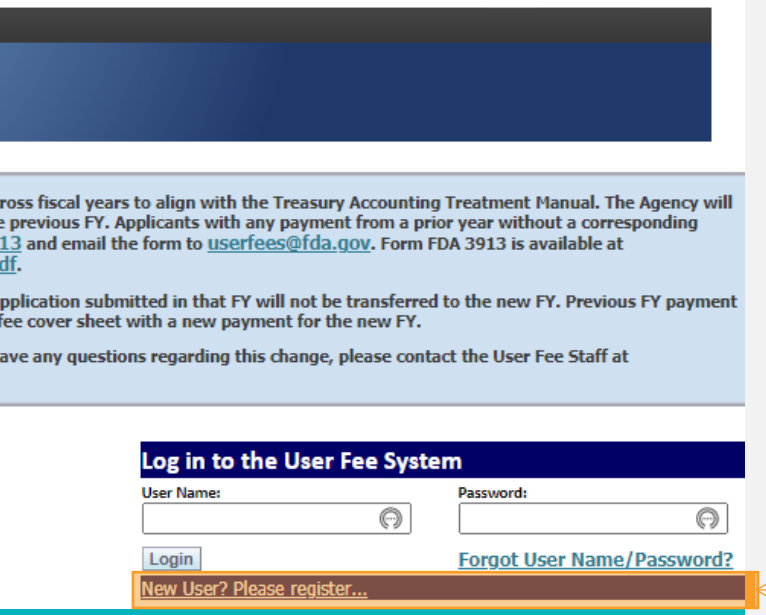
First Things First

Have you paid the user fee before (i.e., do you have a User Fee System Account)?

Unsure?

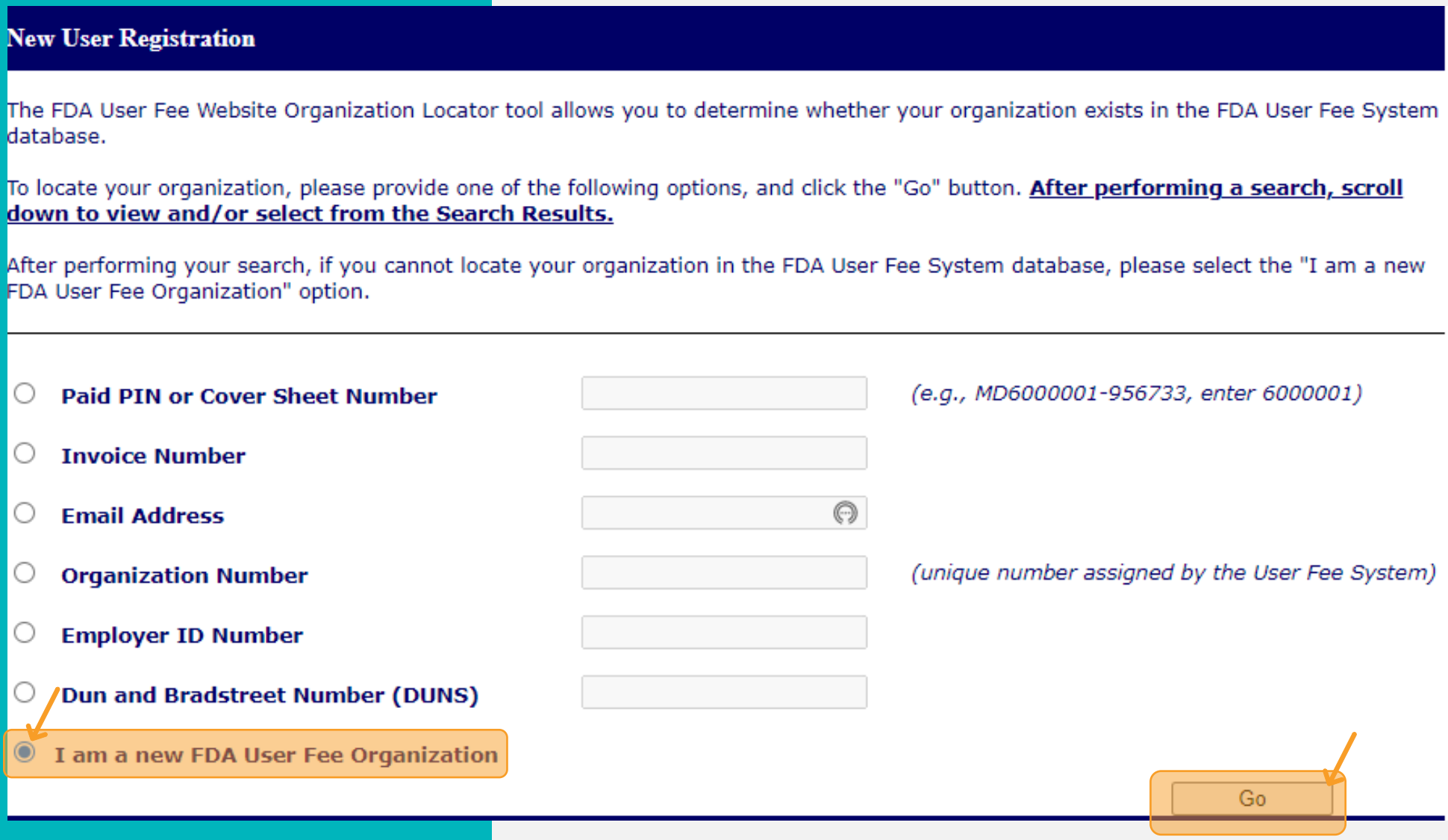
Click on "*New User? Please register…*", then perform a search using one of the following

- **Paid PIN or Cover Sheet #**
- **Invoice #**
- **Email Address**
- **Organization #**
- **Employer ID #**
- **DUNS Number**
  www.fdadunslookup.com



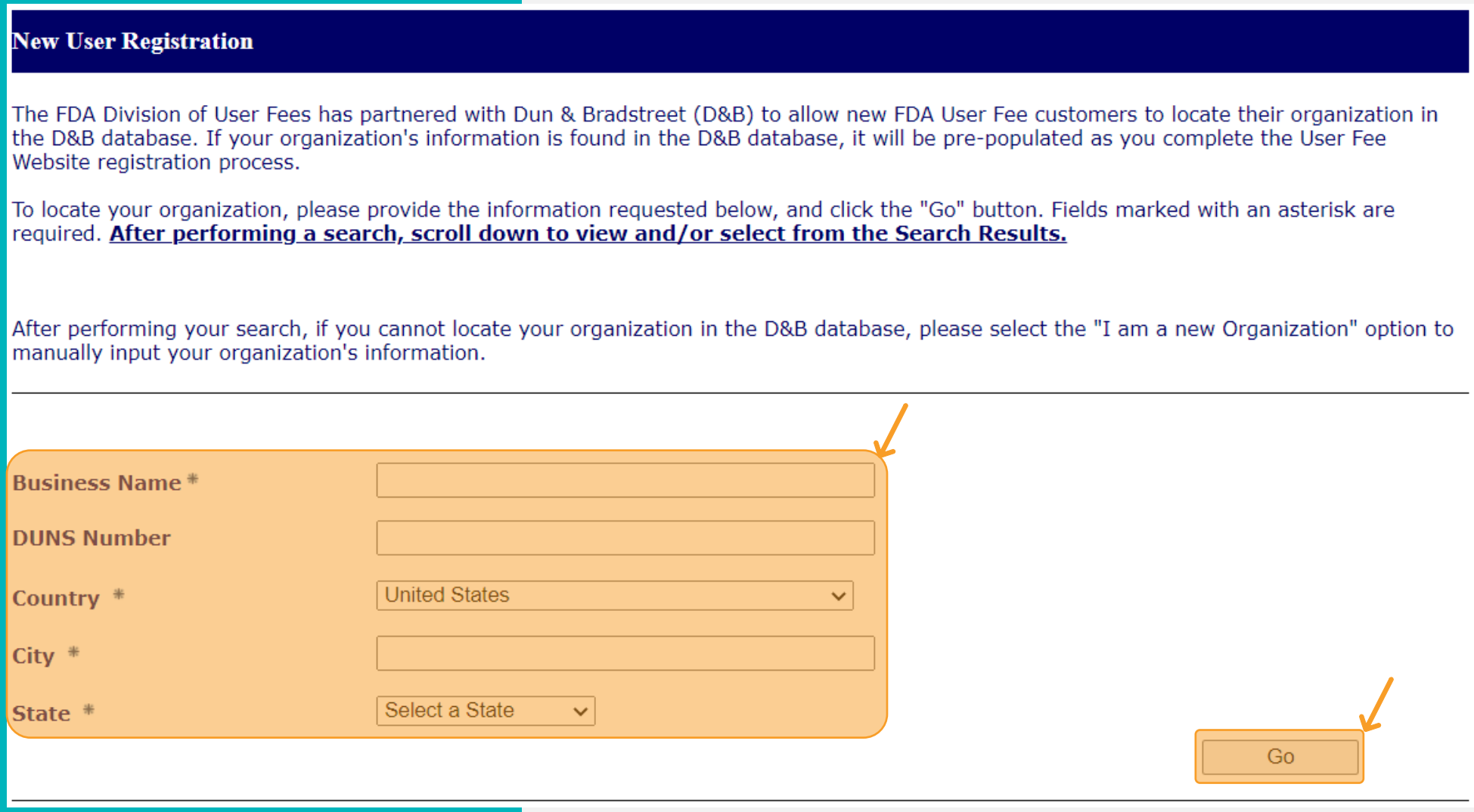
If no results

Click on the "*I am a new FDA User Fee Organization*" radio button, then click "Go"



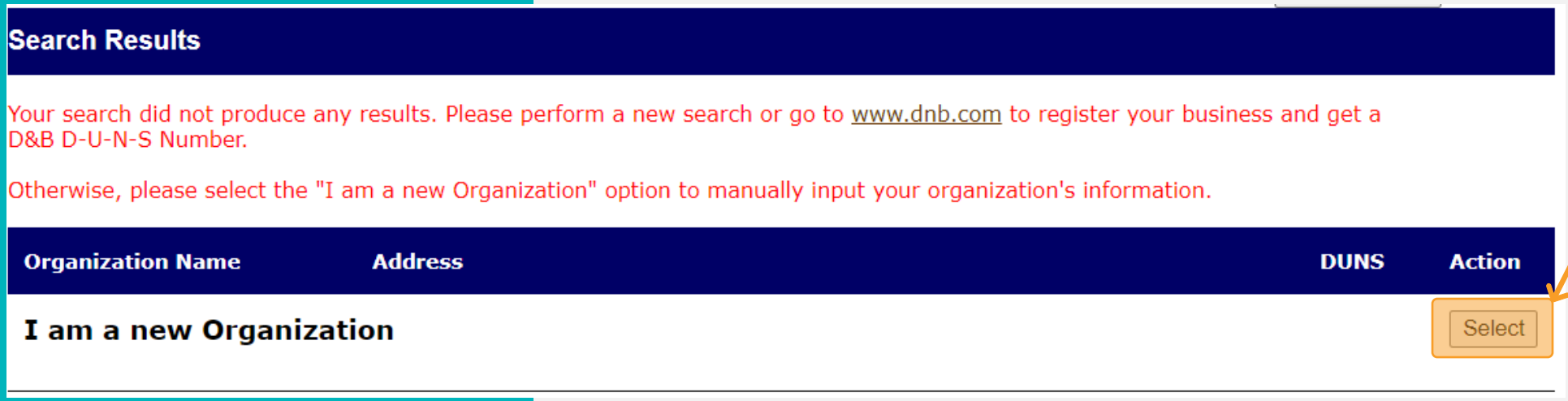
If no results

Fill out the required search fields, then click “Go”



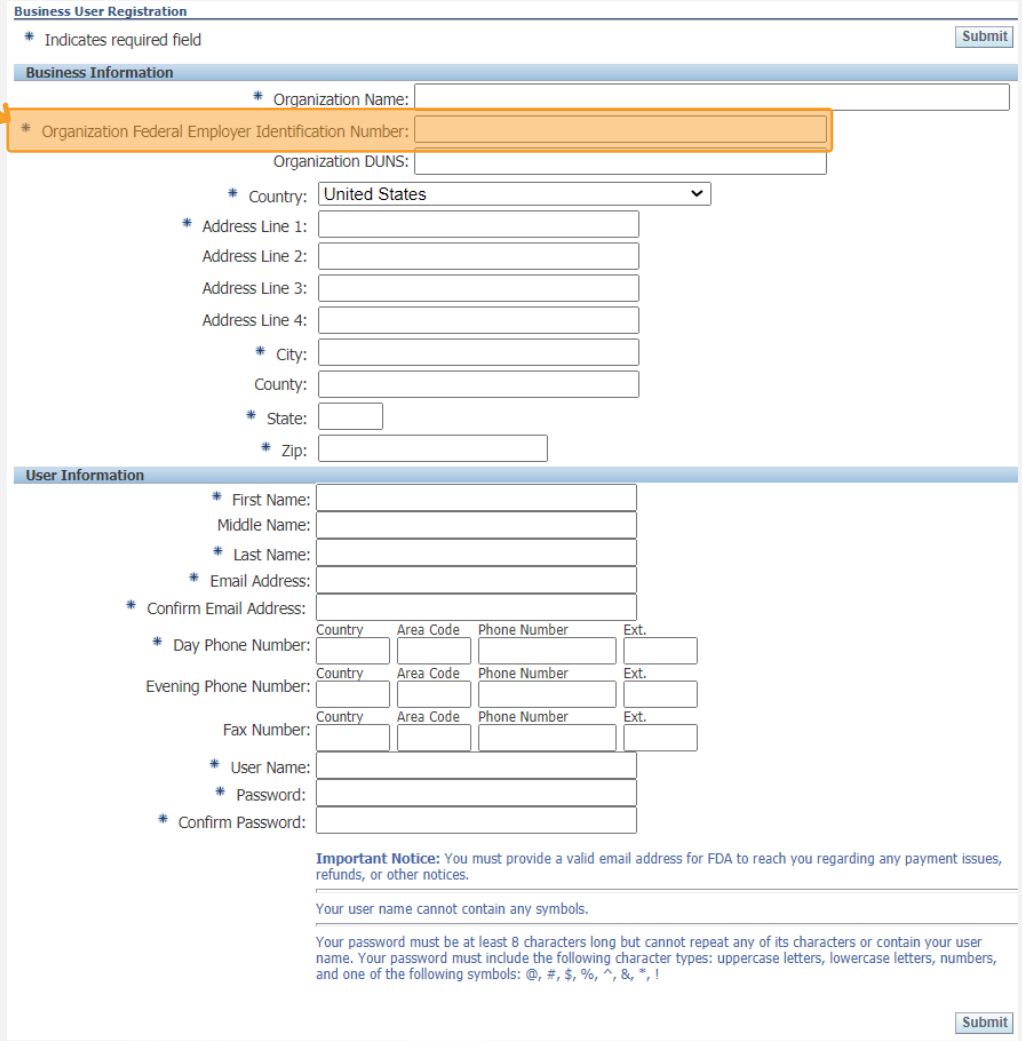
If *STILL* no results

Select "*I am a new Organization*", then click "Go"



Create a new User Fee account

Fill out the required fields, then submit. Note you need your Federal Employer Identification Number (EIN) and it needs to match the EIN on your tax return.



Welcome to your User Fee (MDUFA) Account

You are then logged into the User Fee Website and the FDA User Fees main page.

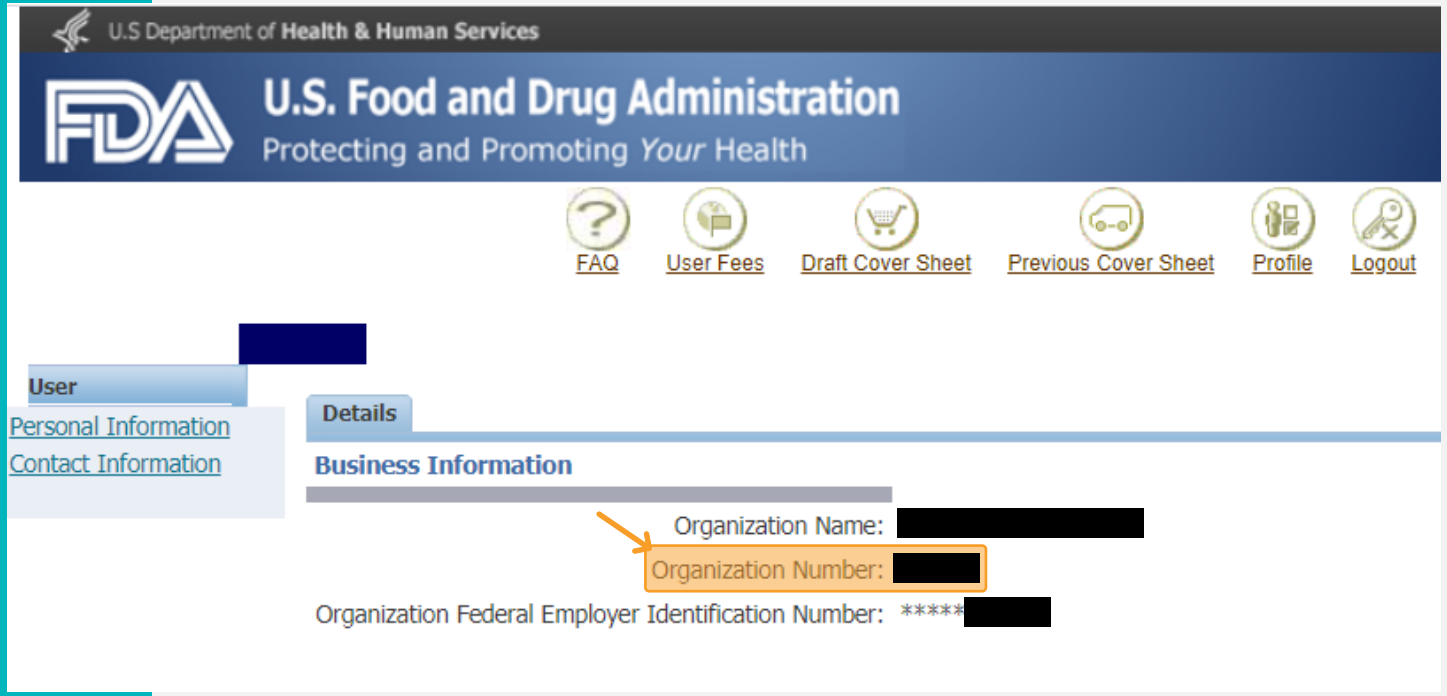
Click “Go” on one of the options

Almost there!

Click on the “Profile” button

This is it!

Your Organization ID number

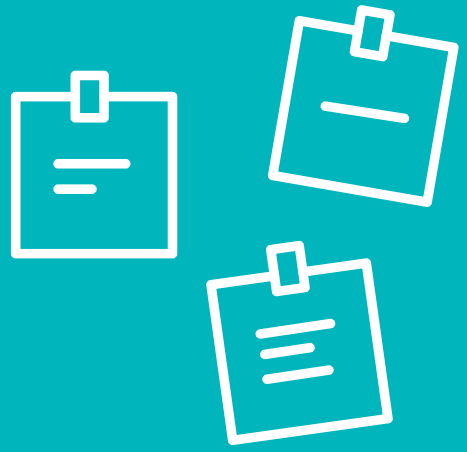


If you're stuck, it's probably time to give us a call.

Michelle Lott
Principal and Founder

520.275.9838
michelle@leanRAQA.com

Detailed steps in
FDA User Fee Account Creation Process User Guide



Note your Organization ID number on a post-it and let's continue, shall we?

Small Business Request for U.S. firms

Small Business Request for U.S. Firms

Complete FDA Form 3602

- If your business is a(n) Inc, LLC, partnership, or other legal entity, provide the name used in its articles of incorporation, articles of organization, partnership registration, or other similar instrument filed with the State or other government under whose laws the firm was created.

- If the business is a sole proprietorship owned entirely by one individual, provide the name used when filing Federal, State, or other taxes.

Small Business Request for U.S. Firms

Complete FDA Form 3602

+ Attach supporting materials showing "gross receipts or sales" of no more than $100 million

IRS Form	See Line Number
Schedule C (Form 1040)	1
Schedule C-EZ (Form 1040)	1
Form 1065	1a
Form 1065-B	1a
Form 1120	1a
Form 1120-F	Section II, 1a
Form 1120S	1a
Form 990	12
Any other form	*contact FDA*

Line # refers to line of the IRS Form

Form 990 is required for tax-exempt firms. Taxpayer ID number in the United States and outside the United States (Section 11(b)).

Small Business Request for U.S. Firms

Complete FDA Form 3602

Most recent business tax return

- Attach a **true and accurate copy (a complete and unaltered copy)** of the business's most recent Federal (U.S.) income tax return. FDA cannot accept a foreign tax return instead of a Federal (U.S.) income tax:
  - 2022 Tax return if qualification application is submitted prior to April 15, 2023 and you have not yet filed your 2022 tax return
  - 2022 Tax return if qualification application is submitted on or after April 15, 2023 OR you filed your 2023 tax return
  - Extensions require 2021 Tax return & IRS Form 7004

What if it’s going to be my first tax year (no tax return yet)?

Small Business Request for U.S. Firms

Complete FDA Form 3602

- A tax return is needed in order to apply for SBD. A personal tax return that includes the company's tax form for Schedule C is acceptable as well.

- If your company has been in business for less than a year, the applicable date range must be found on the return. Provide documentation identifying the businesses formation to justify the lack of a full year's tax return.

Small Business Request for U.S. Firms

Complete FDA Form 3602

- **A tax return is required for every year you take advantage of the SBD. Therefore, consider filing taxes even if it is not required (i.e., the business did not make money).**

Small Business Request for U.S. Firms

Complete FDA Form 3602

Other supporting materials:

- Federal (U.S.) income tax return for each U.S. affiliate
- Certified Section III of FDA Form 3602A for each foreign affiliate
- e-file form submitted to the IRS may be used if it includes a dated signature of an officer, partner or member

Small Business Request for foreign firms

Small Business Request for Foreign Firms

Complete FDA Form 3602A

Send FDA Form 3602A to your National Taxing Authority for Certification of Section III

National Taxing Authority then returns your FDA Form 3602A

Submit FDA Form 3602A to FDA + supporting materials including US Tax return for US affiliates and Certified Section III for non-US affiliates

Phew.

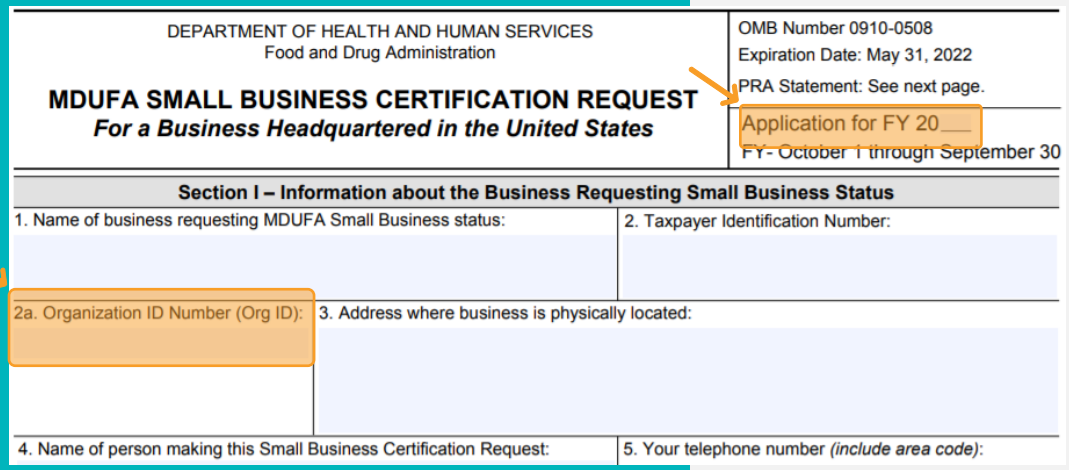
You should be halfway through your bottle at this step.

If not, please let us know how you're coping.

Ready to send your Small Business Request (+ all supporting materials)?

Don’t forget

- **Fill out top right corner field: FY 2024**
- **The Organization ID Number is the one you retrieved/created on the User Fee System**
- **Sign with wet (i.e., ink) or a valid digital signature**



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

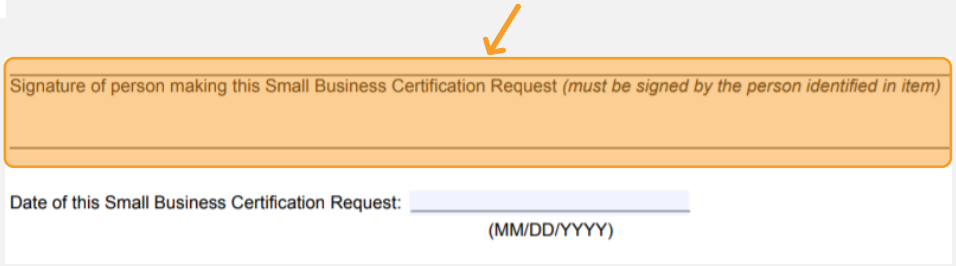
MDUFA SMALL BUSINESS CERTIFICATION REQUEST
For a Business Headquartered in the United States

OMB Number 0910-0508
Expiration Date: May 31, 2022
PRA Statement: See next page.

Application for FY 20___
FY- October 1 through September 30

Section I – Information about the Business Requesting Small Business Status

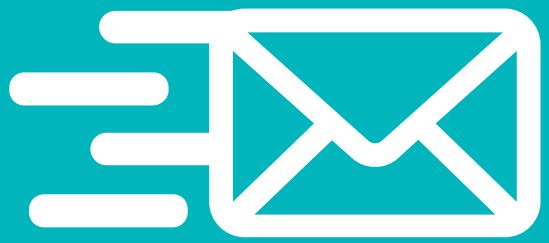
1. Name of business requesting MDUFA Small Business status:	2. Taxpayer Identification Number:
2a. Organization ID Number (Org ID):	3. Address where business is physically located:
4. Name of person making this Small Business Certification Request:	5. Your telephone number *(include area code)*:



Signature of person making this Small Business Certification Request *(must be signed by the person identified in item)*

Date of this Small Business Certification Request: _____
(MM/DD/YYYY)

Send application form and supporting materials to:



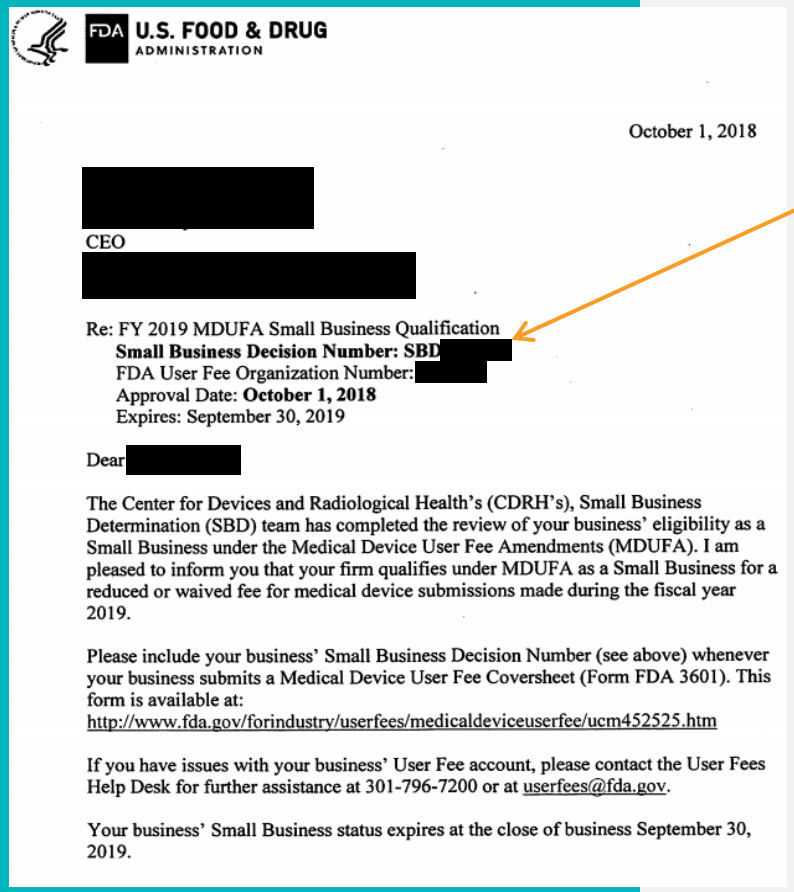
Mail to:

FY 2024 MDUFA Small Business Qualification
Small Business Certification Program
10903 New Hampshire Avenue
Building 66, Room 5305
Silver Spring, MD 20993
U.S.A.

Now what?

You should receive a letter with a small busines decision (SBD) number within 60 days (sometimes faster).

SBDXXXXXX



FDA U.S. FOOD & DRUG ADMINISTRATION

October 1, 2018

[redacted]
CEO
[redacted]

Re: FY 2019 MDUFA Small Business Qualification
Small Business Decision Number: SBD[redacted]
FDA User Fee Organization Number:[redacted]
Approval Date: **October 1, 2018**
Expires: September 30, 2019

Dear [redacted]

The Center for Devices and Radiological Health's (CDRH's), Small Business Determination (SBD) team has completed the review of your business' eligibility as a Small Business under the Medical Device User Fee Amendments (MDUFA). I am pleased to inform you that your firm qualifies under MDUFA as a Small Business for a reduced or waived fee for medical device submissions made during the fiscal year 2019.

Please include your business' Small Business Decision Number (see above) whenever your business submits a Medical Device User Fee Coversheet (Form FDA 3601). This form is available at:
http://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/ucm452525.htm

If you have issues with your business' User Fee account, please contact the User Fees Help Desk for further assistance at 301-796-7200 or at userfees@fda.gov.

Your business' Small Business status expires at the close of business September 30, 2019.

NOW you can pay a reduced fee for your submission

- Your SBD number is required to verify you are qualified for a fee reduction and to complete Medical Device User Fee Cover Sheet (FDA Form 3601)
- A copy of FDA Form 3601 is included with your medical device submissions e.g., 513(g) or 510(k)
- Your payment identification number (PIN) is found on FDA Form 3601 You will need it for the CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)

Credit card

(VISA, MasterCard, AMEX or Discover) and/or Automated Clearing House (ACH) electronic check (eCheck)

Go to:

www.Pay.gov

After submitting your cover sheet click the 'Pay Now' button and follow the instructions to make payment.

To pay later, log into your MDUFA User Fee account and access your cover sheet history page by clicking on the 'Previous Cover Sheets' icon at the top of the page.

Click the 'Pay Now' link next to the PIN number you need to pay for.

Confirmation of payment made by credit card/electronic check can be received in as little as 48 hours.

Wire transfer

Note: FDA's tax identification number is 53-0196965

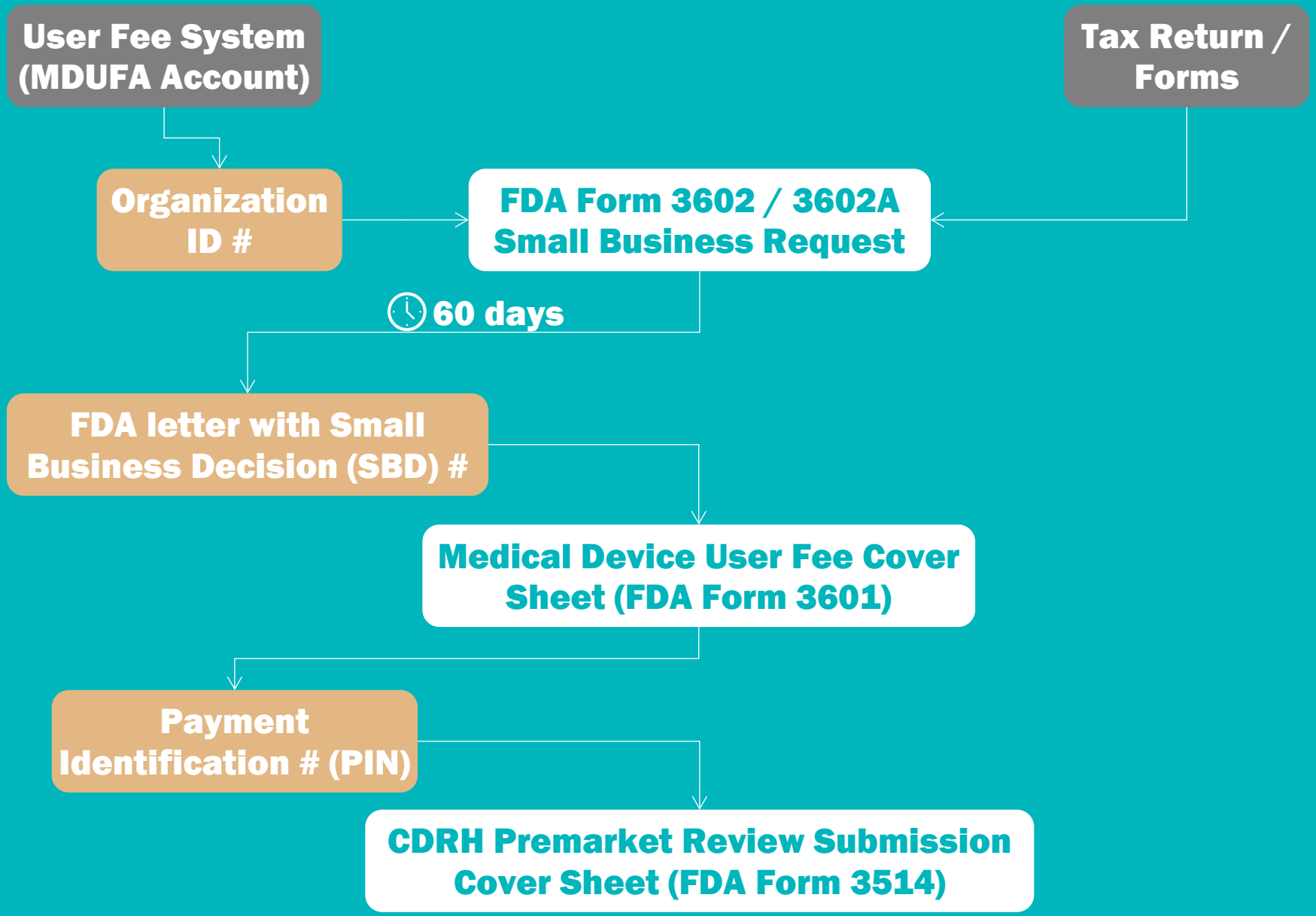
Please include/reference your MDUFA cover sheet PIN with your wire transfer and send to following address:

New York Federal Reserve Bank
US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045

FDA Deposit Account Number: 75060099
US Department of Treasury Routing/Transit number: 021030004
SWIFT Number: FRNYUS33

Beneficiary:
Food and Drug Administration
8455 Colesville Road
COLE-14-14253
Silver Spring, MD 20993-0002

In summary



Hip hip hooray!

You did it. Time to refresh your drink.

References

Small Business Program:
https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program

FDA guidance document:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification

Medical Device User Fee Amendments (MDUFA)
https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa

Division of Industry and Consumer Education (DICE)
+1 (800) 638-2041 or +1 (301) 796-7100
DICE@fda.hhs.gov

FDA Help Desk
+1 (301) 796-7200
userfees@fda.gov

leanRAQA

REGULATORY. STRATEGY.

Put 'em together and what have you got?
A competitive advantage, that's what!

Michelle Lott
Principal and Founder

520.275.9838
michelle@leanRAQA.com