

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	\$108,801 (75% off)
PMA	\$483,560	\$120,890	\$362,670 (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?

When should I renew?



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



**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

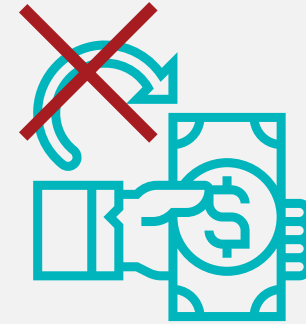


Obtaining a Small Business status is NOT the same thing as doing your Establishment Registration, which is done in FURLS once commercialization has started and then each year between Oct. 1 and Dec. 31.



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



U.S. Department of Health & Human Services



U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

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.



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

No

Log in to retrieve your Organization ID Number

Create your User Fee System Account

Skip to page 17

Log in to the User Fee System

User Name:

Password:

Login

[Forgot User Name/Password?](#)

[New User? Please register...](#)

cross fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will
e previous FY. Applicants with any payment from a prior year without a corresponding
13 and email the form to userfees@fda.gov. Form FDA 3913 is available at
df.

pplication submitted in that FY will not be transferred to the new FY. Previous FY payment
fee cover sheet with a new payment for the new FY.

ave any questions regarding this change, please contact the User Fee Staff at

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

cross fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will
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Log in to the User Fee System

User Name:

Password:

Login

[Forgot User Name/Password?](#)

[New User? Please register...](#)

If no results

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

New User Registration

The FDA User Fee Website Organization Locator tool allows you to determine whether your organization exists in the FDA User Fee System database.

To locate your organization, please provide one of the following options, and click the "Go" button. **After performing a search, scroll down to view and/or select from the Search Results.**

After performing your search, if you cannot locate your organization in the FDA User Fee System database, please select the "I am a new FDA User Fee Organization" option.

<input type="radio"/>	Paid PIN or Cover Sheet Number	<input type="text"/>	<i>(e.g., MD6000001-956733, enter 6000001)</i>
<input type="radio"/>	Invoice Number	<input type="text"/>	
<input type="radio"/>	Email Address	<input type="text"/>	
<input type="radio"/>	Organization Number	<input type="text"/>	<i>(unique number assigned by the User Fee System)</i>
<input type="radio"/>	Employer ID Number	<input type="text"/>	
<input type="radio"/>	Dun and Bradstreet Number (DUNS)	<input type="text"/>	
<input checked="" type="radio"/>	I am a new FDA User Fee Organization		

If no results

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

New User Registration

The FDA Division of User Fees has partnered with Dun & Bradstreet (D&B) to allow new FDA User Fee customers to locate their organization in the D&B database. If your organization's information is found in the D&B database, it will be pre-populated as you complete the User Fee Website registration process.

To locate your organization, please provide the information requested below, and click the "Go" button. Fields marked with an asterisk are required. **After performing a search, scroll down to view and/or select from the Search Results.**

After performing your search, if you cannot locate your organization in the D&B database, please select the "I am a new Organization" option to manually input your organization's information.



Business Name *


DUNS Number

Country * United States

City *

State * Select a State

Go



If *STILL* no results

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

Search Results

Your search did not produce any results. Please perform a new search or go to www.dnb.com to register your business and get a D&B D-U-N-S Number.

Otherwise, please select the "I am a new Organization" option to manually input your organization's information.

Organization Name	Address	DUNS	Action
I am a new Organization			<input type="button" value="Select"/>

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.

Business User Registration

* Indicates required field Submit

Business Information

* Organization Name:

* Organization Federal Employer Identification Number:

Organization DUNS:

* Country:

* Address Line 1:

Address Line 2:

Address Line 3:

Address Line 4:

* City:

County:

* State:

* Zip:

User Information

* First Name:

Middle Name:

* Last Name:

* Email Address:

* Confirm Email Address:

* Day Phone Number:

Country	Area Code	Phone Number	Ext.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Evening Phone Number:

Country	Area Code	Phone Number	Ext.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Fax Number:

Country	Area Code	Phone Number	Ext.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

* User Name:

* Password:

* Confirm Password:

Important Notice: You must provide a valid email address for FDA to reach you regarding any payment issues, refunds, or other notices.

Your user name cannot contain any symbols.

Your password must be at least 8 characters long but cannot repeat any of its characters or contain your user name. Your password must include the following character types: uppercase letters, lowercase letters, numbers, and one of the following symbols: @, #, \$, %, ^, &, *, !

Submit

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

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

User Fee Website

Welcome Fee User

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2016	FURLS Device Facility User Fee	Go

2015 Cover Sheets

FY 2015 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2014 through September 30th, 2015.

User Fee	Description	
Generic Drug User Fee 2015	GDUFA Cover Sheets	Go

2016 Cover Sheets

FY 2016 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2015 through September 30th, 2016.

User Fee	Description	
Animal Drug User Fee 2016	ADUFA Pre-Market Cover Sheets	Go
Animal Generic Drug User Fee 2016	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2016	BsUFA Cover Sheets	Go
Generic Drug User Fee 2016	GDUFA Cover Sheets	Go
Medical Device User Fee 2016	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2016	PDUFA Pre-Market Cover Sheets	Go

Almost there!



Click on the “Profile” button

The screenshot shows the FDA website header with the text "U.S. Department of Health & Human Services" and "U.S. Food and Drug Administration Protecting and Promoting Your Health". A navigation bar contains icons for "FAQ", "User Fees", "Draft Cover Sheet", "Previous Cover Sheet", "Profile", and "Logout". An orange arrow points to the "Profile" button. Below the navigation bar, a "User Fee Websites" sidebar lists links for "Food and Drug Administration", "Center for Biologics Evaluation and Research", and "Center for Devices and Radiological Health". The main content area features a message about policy changes for fiscal year 2021, followed by "Go Back" and "Continue" buttons.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheet **Profile** Logout

Medical Device

User Fee Websites

- [Food and Drug Administration](#)
- [Center for Biologics Evaluation and Research](#)
- [Center for Devices and Radiological Health](#)

Please review the important message below regarding a change in policy on payment transfers across FYs before proceeding to the next step.

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to userfees@fda.gov. Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

Starting in FY 2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Click "Continue" if you still want to proceed with creating your cover sheet or click "Go Back" to choose the correct FY's cover sheet.

This is it!



Your Organization ID number

A screenshot of the FDA user profile page. The header includes the U.S. Department of Health & Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration" and "Protecting and Promoting Your Health". Below the header are navigation icons for FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. The main content area shows a user profile with tabs for "User", "Personal Information", "Contact Information", and "Details". The "Details" tab is active, and the "Business Information" section is expanded. An orange arrow points to the "Organization Number" field, which is highlighted with an orange box. The "Organization Name" and "Organization Federal Employer Identification Number" fields are also visible, with the latter showing "****" followed by a redacted area.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

[FAQ](#) [User Fees](#) [Draft Cover Sheet](#) [Previous Cover Sheet](#) [Profile](#) [Logout](#)

User [Redacted]

[Personal Information](#)
[Contact Information](#)

Details

Business Information

Organization Name: [Redacted]

Organization Number: [Redacted]

Organization Federal Employer Identification Number: **** [Redacted]

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

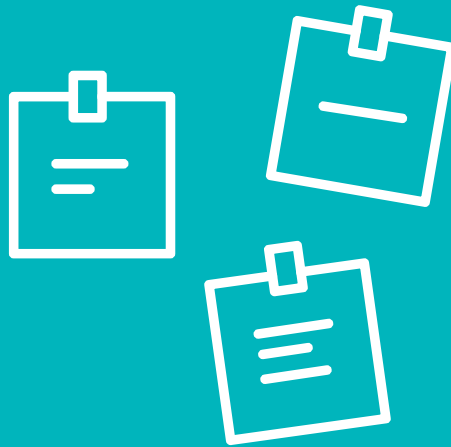


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**Detailed steps in
FDA User Fee Account Creation
Process User Guide**



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	<i>contact FDA</i>

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)?

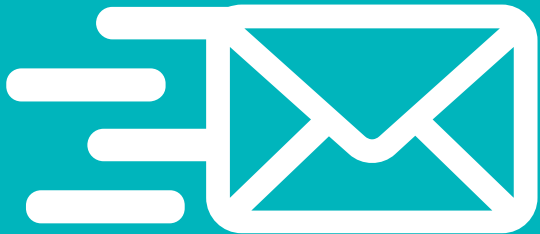
Don't forget

- **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		OMB Number 0910-0508 Expiration Date: May 31, 2022 PRA Statement: See next page.
MDUFA SMALL BUSINESS CERTIFICATION REQUEST <i>For a Business Headquartered in the United States</i>		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:**



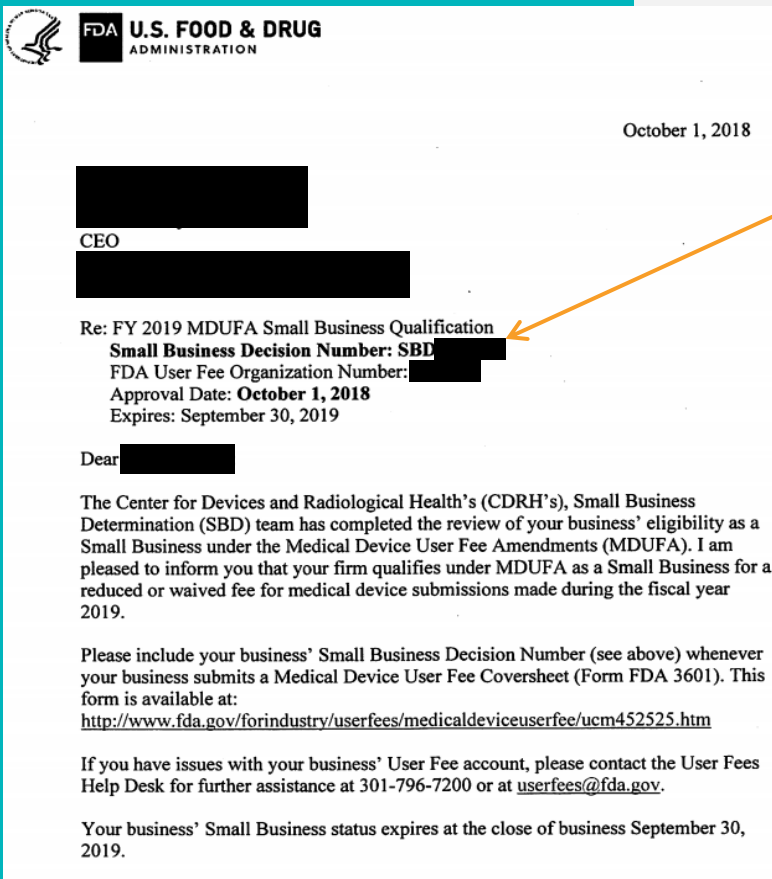
Mail to:

**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 business decision (SBD) number within 60 days (sometimes faster).**

SBDXXXXXX





**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

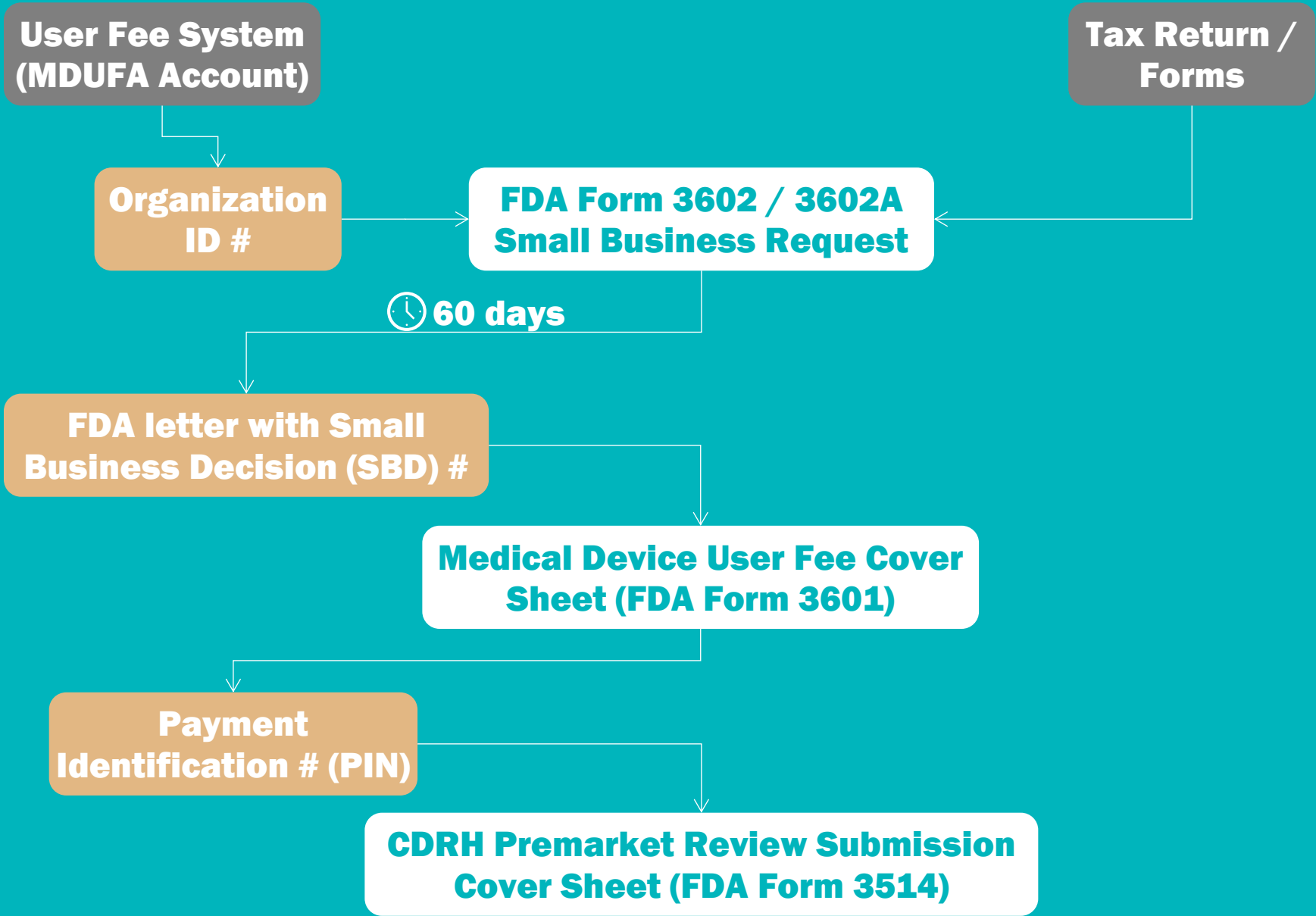
Please include/reference your MDUFA cover sheet PIN with your wire transfer and send to following address:

**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**

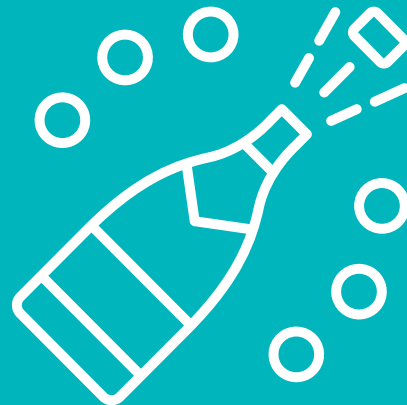
In summary





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



REGULATORY. STRATEGY.

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



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