•	CCP - Dashboard X	+								- 0
←	→ C scp-mig.preprod.fd	la.gov/prweb/PRAuth/app/CCP_/g	7zcEWmuc411AfZHOtpxdmVOlsgyM2	2cr*/!STANDARD					९ ☆	<u>۵</u>
FDA	Welcome, Nis	hma Nishma								
+	Your reviews									
	16 Records							Active reviews only	(default)	> Fields
	ID 😧	Received date	Progress	E	Туре 🚦	Track 🚦	Goal date	Days 🚦	More info	÷
	SBR-2024-000188	Tue May 28, 2024	Processing		Small Business Request		Sat Jul 27, 2024			
	SBR-2024-000144	Thu May 23, 2024	Processing		Small Business Request		Mon Jul 22, 2024	-		
	SBR-2024-000145	Thu May 23, 2024	Processing		Small Business Request		Mon Jul 22, 2024			
	SBR-2024-000141	Thu May 23, 2024	Processing		Small Business Request		Mon Jul 22, 2024			
	SBR-2024-000142	Thu May 23, 2024	Processing		Small Business Request		Mon Jul 22, 2024			

CCP Home Page - Your Reviews Section (Industry user will be provided access upfront for CCP application)

Click Start for Small Business Determination(SBD) request

~	Create a request × +		-	٥	×
÷	C ccp-mig.preprod.fda.gov/prweb/PRAuth/app/CCP/g7zcEWmuc411A/ZHOtpxdmVOlsgyM2cr*/ISTANDARD Q	. ☆	Ð	2	÷
FD/ 4 +	Create a request Select an application to start a new request.				
	Small Business Determination (SBD) request Use this form to determine whether your business is qualified and certified as a "small business" and eligible for a reduced fee for some types of CDRH submissions.		St	art	
	Total Product Life Cycle Advisory Program (TAP) application Use this form if your device has been granted a Breakthrough Device designation.		St	art	

Navigates to Basic Qualification Section- Enter \$ amount, select country name from the drop down, enter unique Org ID and click Next to continue or Save to save the draft

G	ccp-mig.preprod.fda.gov/prweb/PRAuth/app/sbdext/bhyjR-F9jdXycAABfLfAPQs0pN5dcF-5*/lautoThread0?pzuiad	ctionzzz=CXtycX0wZTJiNDc
Sm	all Business Determination (SBD) request	
Fields	are required unless noted as (optional).	
Bas	ic qualifications	
For the	e most recent tax year, what are the estimated total gross receipts and sales ur business and its affiliates (if you have affiliates)?	
\$345	,567.00	
Where	e is your business physically located?	
Ando	rra 🗸	
Organ	ization ID number ("Org ID")	
3524	24636	
For w	nich Fiscal vear are vou applving?	
20	25	
Canc	el request	Save Next

User will be navigated to 'Business Information' Section - Fill out all the information and click 'Next' to continue

Fields are required unless noted as (optional). Select any step	in the progress bar to go back and edit your information.		
Basic qualifications	Business information	Upload files	
Business information			
Company information			
Company name (legal entity) 💡	Organization ID number ("Org ID")		
Physical address			
Address line 1			
Address line 2 (optional)			
City	Postal code Pr	rovince/region	

User will be navigated to 'Upload files' section - Click Upload files' button to upload the files (Place where user will be able to upload 3602 and 3602A forms)

Small Business Determination	ı (SBD) request	
Basic qualifications	Business information	Upload files
0	0	•
Upload files		
Upload files to support your request.		
Upload files		

Upload files modal will pop up - Upload the files and modal will get closed

Upload files			
 Each file must be less than 2GB. Larger files n Allowable file types - pdf. 	nust be shipped to FDA		
	@ Drag & drop a file here, or browse	for it.	
	• • • • • • •		
Files 0			
	Upload files • Each file must be less than 2GB. Larger files • Allowable file types - pdf.	Upload files • Each file must be less than 2GB. Larger files must be shipped to FDA • Allowable file types - pdf.	Upload files • Each file must be less than 2GB. Larger files must be shipped to FDA • Allowable file types - pdf.

Verify list of uploaded files - Click 'Next' button to continue and 'Save' to save the draft

← →	G	ccp-mig.preprod.fda.gov/pr	web/PRAuth/app/sbdext/bhyjR·	F9jdXycAABfLfAPQs0pN5dcF	-5*/!autoThread0?pzuiaction	zzz=CXtycX0wZTJiNDd	OThmN2FiNGU4M2I2OTdmYmYv
FDA	Sma	II Business Determi	nation (SBD) reque	st			
	Basic qua	lifications		Business information		Upload files	
	0			0		•	
	Upload f	iles					
	Uploa	id files					
	Uploade	d files 2				C' Refresh	
	File nan	ne	File description (optional)	Size	Uploaded on	Actions	
	4_10_SB	D_Deficiency_Handling_User_Vineet.pdf		4,432 KB	May 30, 2024 02:30 ET	÷	
	Sites-fos	isil-na-Site.pdf	abbc	106 KB	May 30, 2024 02:30 ET	1	
	Cancel	request				Save Next	

User is navigated to 'Review & send to FDA' section - Review the submitted information and click 'Send' from the bottom of the page to submit the request or 'Save' to save the draft

Small Business Determinat	ion (SBD) request		
Basic qualifications	Business information	Upload files	Review & send to
Review & send to FDA		0	
Basic qualifications For the most recent tax year, what are the estimated tot for your business and its affiliates (if you have affiliates) \$345,567.00	al gross receipts and sales		
Where is your business physically located? Andorra For which Fiscal year are you applying? 2025			
Business information			
Company information			
Company name BBC comp			
Organization ID number			

During all these steps user can click on 'Cancel request' to cancel the request

On clicking 'Send' request will be submitted and user will see acknowledgement message and uploaded files will start f

← \rightarrow C ccp-mig.preprod.fda.gov/prweb/PRAuth/app/sbdext/bhyjR-F9jdXycAABfLfAPQs0pN5dcF-5*/!autc

have sent your request. (Sent May 30, 2024 02::	36 ET).
vill send an email confirmation to the primary point	t of contact. We will send an email update within 1 business day.
act ccp@fda.hhs.gov if you have any questions or	feedback.
can see the status of this request on the home pag	e once it has been refreshed.
nay close this browser tab.	

Once virus scan is successful, a case will be created and an acknowledgment email will be sent to POCs emails with Cas

С	Customer Collaboratio To OShah, Nishma *	on Portal <ccp@fda.h< th=""><th>ıs.gov></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>•</th></ccp@fda.h<>	ıs.gov>								•
art your	reply all with: Thank you	for your confirmation.	Here is	the information. Thank you. I lo	ok forward to hearing from you.	(i) Feedback					
С	https://ccp-mig.pre	eprod.fda.gov/prweb/PRAu	th/app/O	CP_/g7zcEWmuc411AfZHOtpxdmVOI	sgyM2cr*/!STANDARD		Q	AN 🏠	3		ć= %
	Welcome, Ni	shma Nishm	a								
Ľ	Your reviews										
Ľ	Your reviews							 Active revi 	ews only	(default)	Field
	Your reviews	Received date	:	Progress	і Туре	Track	i Goal date i	 Active revi Days 	ews only	(default) More i	Field
	Your reviews	Received date	24	Progress Processing	type Small Business Request	Track	Goal date Mon Jul 29, 2024	• Active revi Days	ews only	(default) More i	Field nfo
	Your reviews	E Received date Thu May 30, 20 Tue May 28, 20	1 24 24	Progress Processing Processing	I Type II Small Business Request Small Business Request	Track	i Goal date i Mon Jul 29, 2024 Sat Jul 27, 2024	Active revi Days	ews only	(default) More ii 	Field nfo

For status updates, use this link to access the CDRH Portal home page. If you have questions about your request, email ccp@fda.hhs.gov.

Small Business Determination Program FDA Center for Devices and Radiological Health



352424636

for your business and its affiliates (if you have affiliates)? \$345,567.00

\leftarrow	C	https://ccp-mig.preprod.fda.gov	v/prweb/PRAuth/app/CCP_/g7zcEWmuc411AfZHOtpxdmVOlsgyM2cr*/ISTANDARD	Q	A»	☆	¢		£≡	∞ [€	
FDA		Welcome, Nishma									
+		Your reviews									
		22 Records			▼ Act	ive revie	ews only	(default	.) 💿	Fields	
\leftarrow	С	https://ccp-mig.preprod.fda.gov/	prweb/PRAuth/app/sbdext/bhyjR-F9jdXycAABfLfAPQs0pN5dcF-5*/!autoThread18?pzuiactionzzz=CXtycX1IOTU2ZTE3ZmJjN2 Q	A∌	☆	Ġ		£≡	~	e	
FDA	Small SB Comp fasd Orgar 53624	Business Request R-2024-000237 Dany name (legal entity) nization ID number ("Org ID") 156425	To do 1 Deficiency identified - response required Select start to continue Submission details						Sta		
	SBD R	Reviewer MA SHAH	Basic qualifications							- I	
	nishm	na.shah@fda.hhs.gov1	For the most recent tax year, what are the estimated total gross receipts and sales for your business and its affiliates (if you have affiliates)? \$532-534 00								
	SUDIT	nission details	Where is your business physically located?							- I	
			Albania							- I	
			For which Fiscal year are you applying? 2025								J

When there is a deficiency raised by reviewer home page will show a request 'On hold' as below

Click Start button and click on upload files, this will open modal for file upload, click complete and click send to submit the request or save to save the request.

 https://ccp-mig.preprod.tda.gov/prwed 	у РКАЦП/арр/sbdext/bhyjk-r9jdxycAAbiLiAPQs0ph5	dcF-5"/!autoThread18?pzulactionzzz=CAtycATi	JTUZZTESZMIJINZ		Z= .09	
Small Business Request SBR-2024-000237	Upload files Upload files to support your request.					
Company name (legal entity) fasd	Upload files					
Organization ID number ("Org ID") 5362456425	Uploaded files 1					C' Refresh
SBD Reviewer	File Name	File description (optional)	Size	Uploaded on	Actions	
nishma.shah@fda.hhs.gov1	Form FDA 3602A.pdf	SS	577 KB	May 30, 2024 23:26 ET		÷
Submission details	Cancel request				Save	Send

Once the file is uploaded, virus scanning will be initiated and home page will show the status as 'Processing' **Welcome**, **Nishma**

Your reviews												
22 Records									• A	Active reviews only ((de	fault) 💿 Fields
ID 😧	÷	Received date	ł	Progress	ŧ	Туре	Track	Goal date		Days 🚦	N	Nore info 🚦
SBR-2024-000237		Fri May 31, 2024		Processing		Small Business Request		Tue Jul 30, 2024			-	-

If virus scan fails, it will send an email to industry user and if it is successful then status will change to 'Reviewing' Sometimes, if industry user doesn't have to upload the file then reviewer can move forward in the workflow which will auto resolve the task for industry user