



USER MANUAL

for

EVERS Portal



Everest Minds for digital transformation

February 2, 2023

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1 Introduction

1.1 Project Scope Overview

The registration process of veterinary products currently operates its submissions using a manual non automated process and due to the large amount of in-person submissions and the back-and-forth feedback appointments between the EDA team and the Applicants in a single submission, this hectic process takes a long time to be reviewed and approved.

The EVERS Project is a web portal that helps ease the process of veterinary products registration.

The system will also manage the task distributions and will help in the process of decision making and limits the back and forth communication between both parties.

1.2 Intended Audience and Reading Suggestions

The document addresses The Companies that are going to be using this system. Also EDA users who are going to deal with the system. Basically, anyone who is going to use the EVERS Portal should read this user manual first before login as to make the experience smooth and easy.

2 Company Interface

2.1 Portal overview

The main goal of this project is to facilitate and enhance communication between companies and EDA team during the registration process of veterinary products.

2.1.1 Login Page

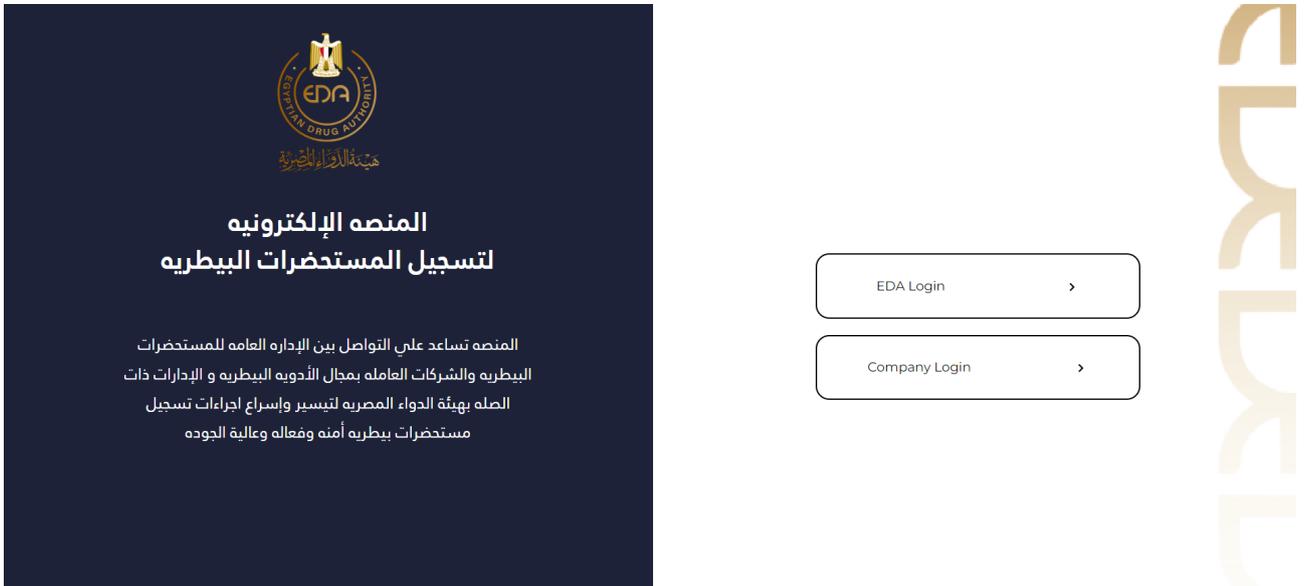


Figure 2.1: First Login page

This is the first page the user encounters once he opens the portal, all the applicants should choose to login as a company which will then direct them to the company login page

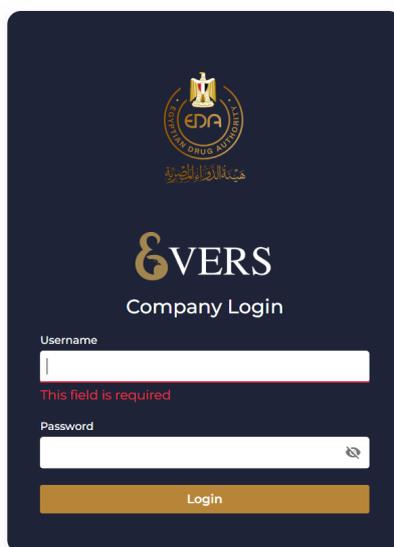


Figure 2.2: Second Login page

Companies can only login to the Portal from the Company Login page, Login will be through company account created in EDA company profile. EDA is responsible to provide each company a user name and a password for login.

2.1.2 Work-list

Application	Trade Name	Registration Type	Marketing Type	Ingredients	Dosage form	Assigned
NT-326	---	Toll	Local	ACETYLCYSTEINE	Absorbable Screw	Jan 24, 20
NT-337	Notification 1	Toll	Export	BISACODYL	Absorbable Suture	Jan 25, 20
NT-247	Ethostatvest Premix	Local	Local	AMPROLIUM-Ethopabate	Premix	Dec 8, 20
NT-248	Spectradox 50%	Local	Local	DOXYCYCLINE	Powder for use in drinking water / milk replacer	Dec 8, 20
NT-249	Fluralaner 250 mg-Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
NT-251	Fluralaner 1000 mg-Eva Pharma	Local	Local	Fluralaner	Chewable Tablet	Dec 8, 20
NT-255	L-Spectin Forte	Local	Local	LINCOMYCIN-SPECTINOMYCIN	Water Soluble Powder	Dec 8, 20
NT-256	Oxytetrex 50% Powder	Local	Local	OXYTETRACYCLINE	Powder for use in drinking water	Dec 8, 20
NT-257	Respotulathril plus	F-toll	Local	Tulathromycin -KETOPROFEN	Solution for injection	Dec 8, 20
NT-258	Marbofloxacin -Mapco	F-toll	Local	Marbofloxacin	Solution for injection	Dec 8, 20

Figure 2.3: My Work list

Once the user logs in he will land on this page: “My Work-list” which is the main page for managing his work, user can find 3 different tabs to do so:

My Assigned Applications (New): This tab contains all the new submissions or tasks that the user must take an action upon.

My Assigned Applications (Resume): This tab contains all the resumed submissions or tasks that the user must take an action upon.

My Assigned Modifications: This tab contains all the modifications that the user must take an action upon.

Ongoing Application: This tab contains all the submissions or tasks the user has already worked on to be able to track the progress of his work and at this point the user can't take any actions on the submission but just view them.

Ongoing Modification: This tab contains all the submissions or tasks the user has already worked on to be able to track the progress of his work and at this point the user can't take any actions on the submission but just view them.

Completed Application: This tab shows only the finished submissions either the ones who completed the workflow and got accepted or the ones who got rejected or canceled.

Completed Modification: This tab shows only the finished modifications either the ones who completed the workflow and got accepted or the ones who got rejected or canceled.

Requested Modification This tab shows the requested modification, modification still waiting either to be accepted or rejected.

2.1.3 Notifications

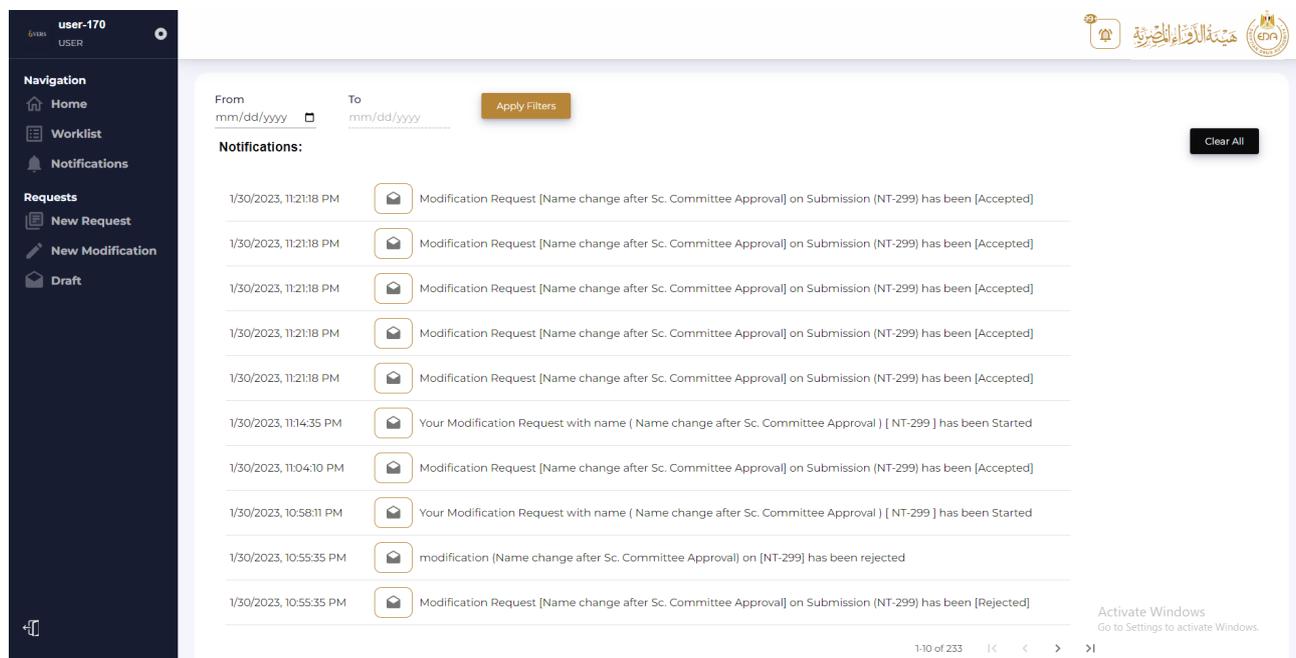


Figure 2.4: Notifications

From the side navigation bar you can access the notifications that are sent to you whenever an action regarding your application occurs or they can be accessed from the top right notification icon. Also, the company will receive an email as a notification each time the submission requires their attention or at the company's side.

2.1.4 New Request

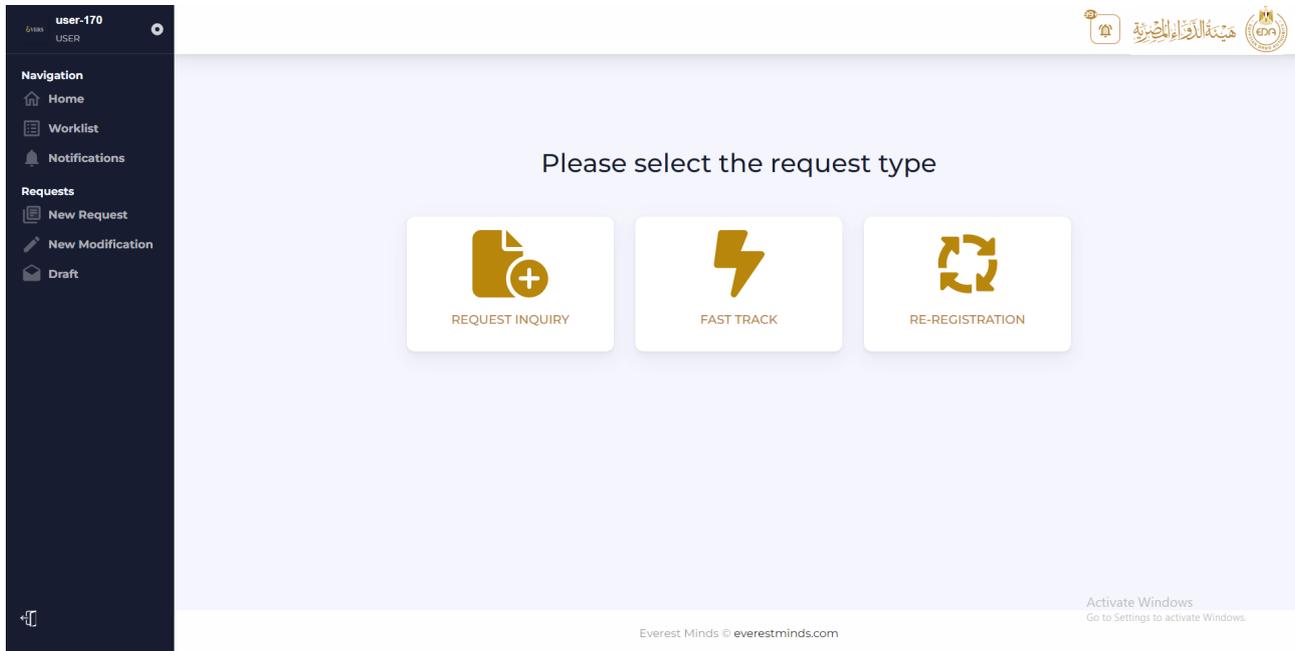


Figure 2.5: Request Inquiry

The company can start a new Inquiry Request from the New Request Tab in the side navigation bar, then they will be able to choose either Local or Export Requests as shown.

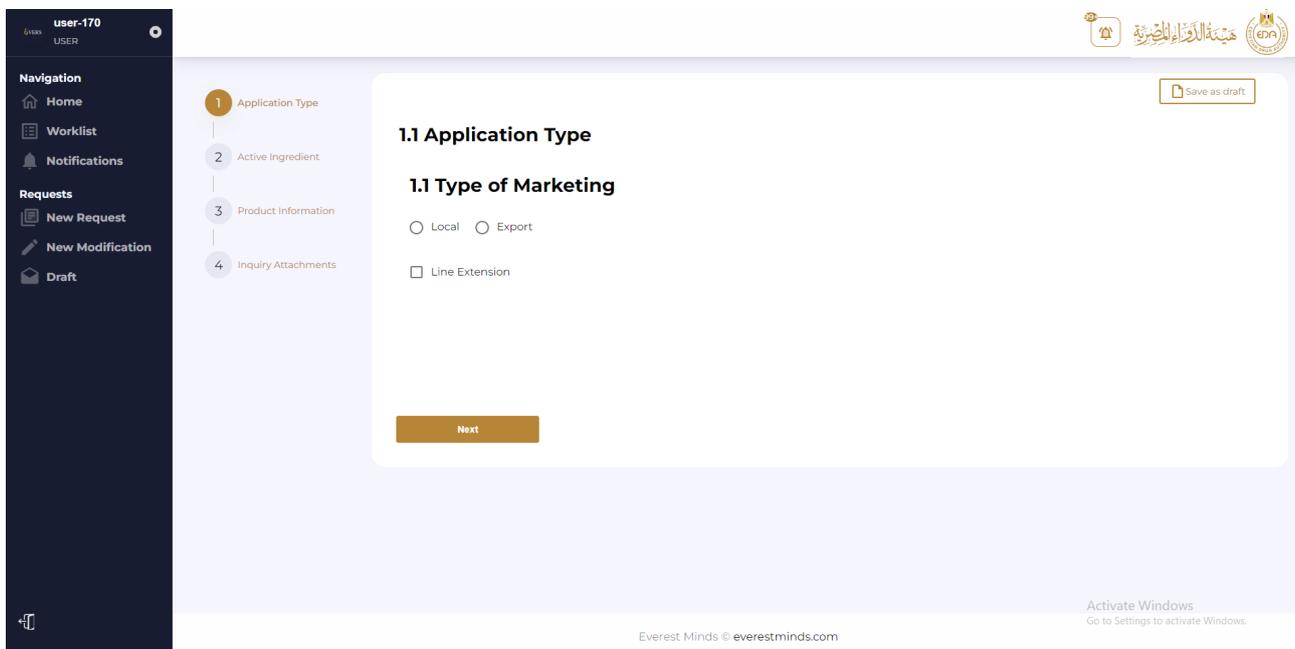


Figure 2.6: Type of Marketing

Then company will be able to choose either Local or Export Requests as shown.

The screenshot shows a web application interface for the Egyptian Drug Authority. On the left is a dark navigation sidebar with options like Home, Worklist, Notifications, and Requests. The main content area is titled '1.1 Application Type' and contains several sections: '1.1 Type of Marketing' with 'Local' selected; '1.2 Type of Registration' with '1.0 Registration Category*' set to 'Local/F-Toll' and '1.2 Type Of Registration*' set to 'Local'; and '1.4 Manufacturers Information' with a dropdown for 'Manufacturer Name *'. A 'Save as draft' button is in the top right, and a Windows activation notice is in the bottom right.

Figure 2.7: Type of Registration

After choosing the type of marketing, you should choose the registration category in the type of registration (Local or Toll). Then you can choose whether the type of registration is Local or F-toll. You should tick the checkbox if you're still under construction. Please note that each entry affects the required inquiry attachments later on.

This screenshot is similar to Figure 2.7 but shows a different selection. In the '1.2 Type Of Registration*' section, the 'Toll' radio button is now selected. The '1.0 Registration Category*' remains 'Local/F-Toll'. The 'Manufacturer Name *' dropdown is also visible.

Figure 2.8: Registration category

Depending on the type of registration, you'll be guided through Manufacturer's information.

Figure 2.9: Manufacturers Information

Products with imported as registration type will allow you to enter the trade name as this submission will skip the naming process.

The manufacturer's information change according to the type of registration.

Figure 2.10: Imported bulk as the registration type

Please note that the red asterisk means that this file is mandatory which means that you could not submit unless you upload all the mandatory files.

Figure 2.11: Imported as the registration type

Please note that the red asterisk means that this file is mandatory which means that you could not submit unless you upload all the mandatory files.

Figure 2.12: Export as type of marketing

Once the application is filled successfully and all the mandatory fields are filled the user can then submit his application and he will then get the following message notifying him that the application is now submitted as shown.

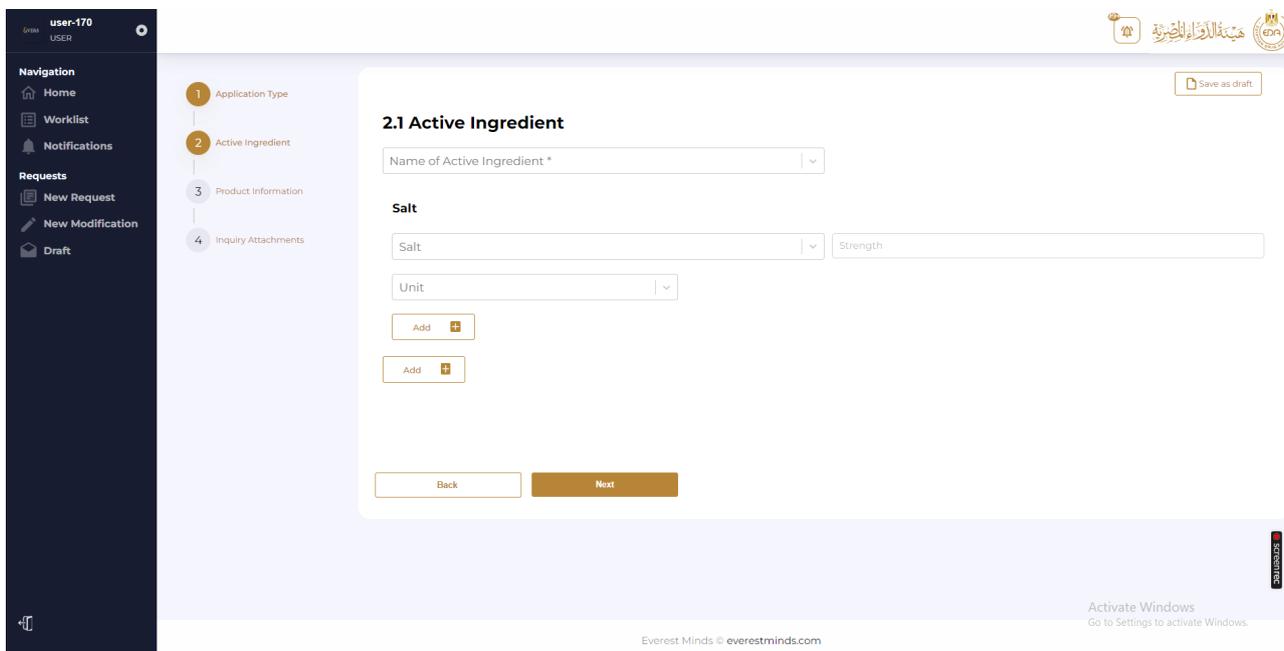


Figure 2.13: Active ingredient

Use the drop down list to choose your active ingredient and salt.

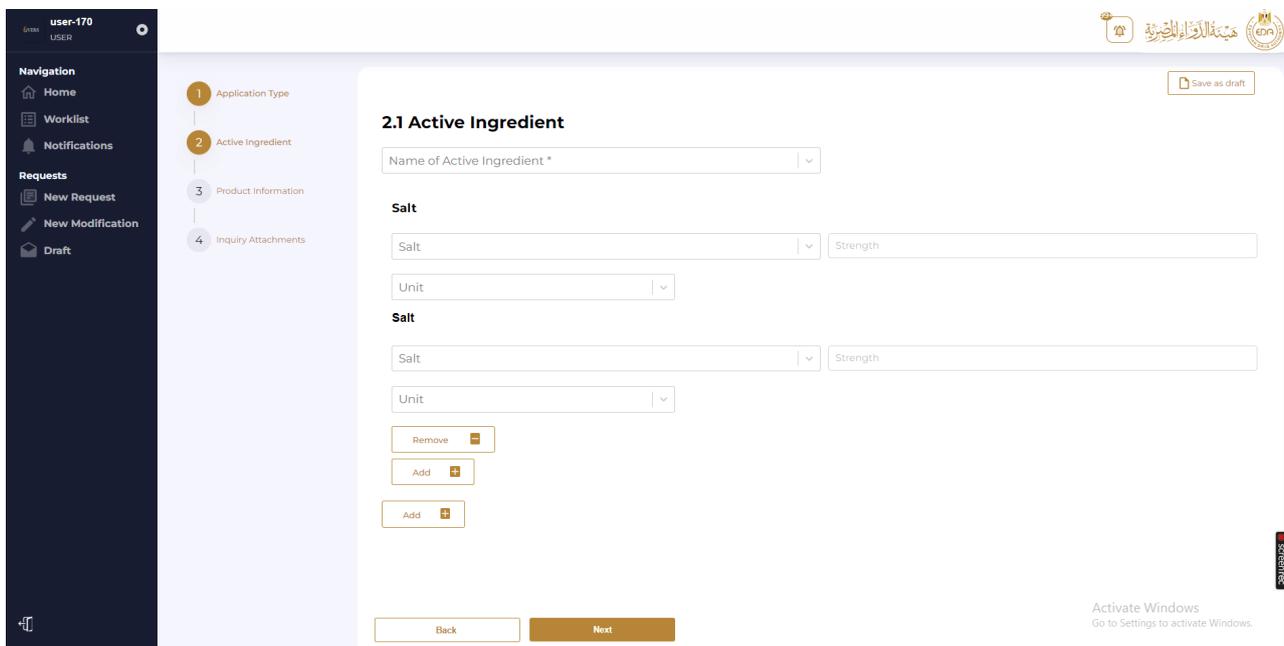


Figure 2.14: More than one Salt

There is an option where you can add or remove more than one salt.

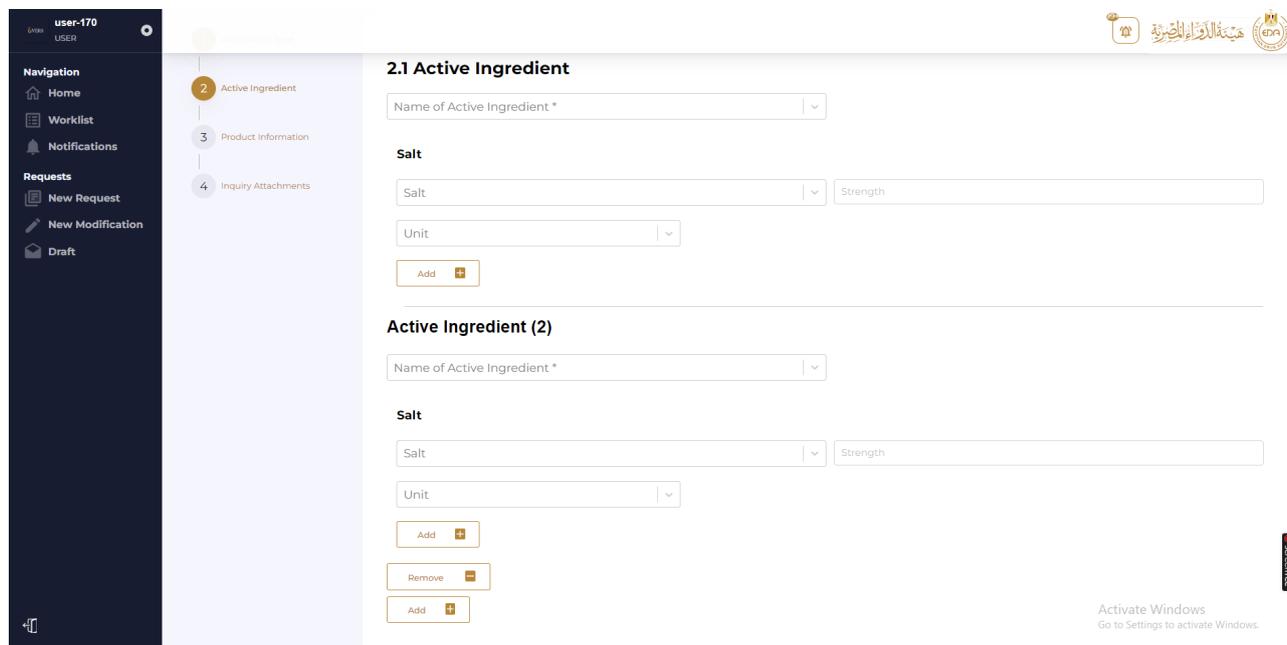


Figure 2.15: More than one Active ingredient

There is an option where you can add or remove more than one active ingredient.

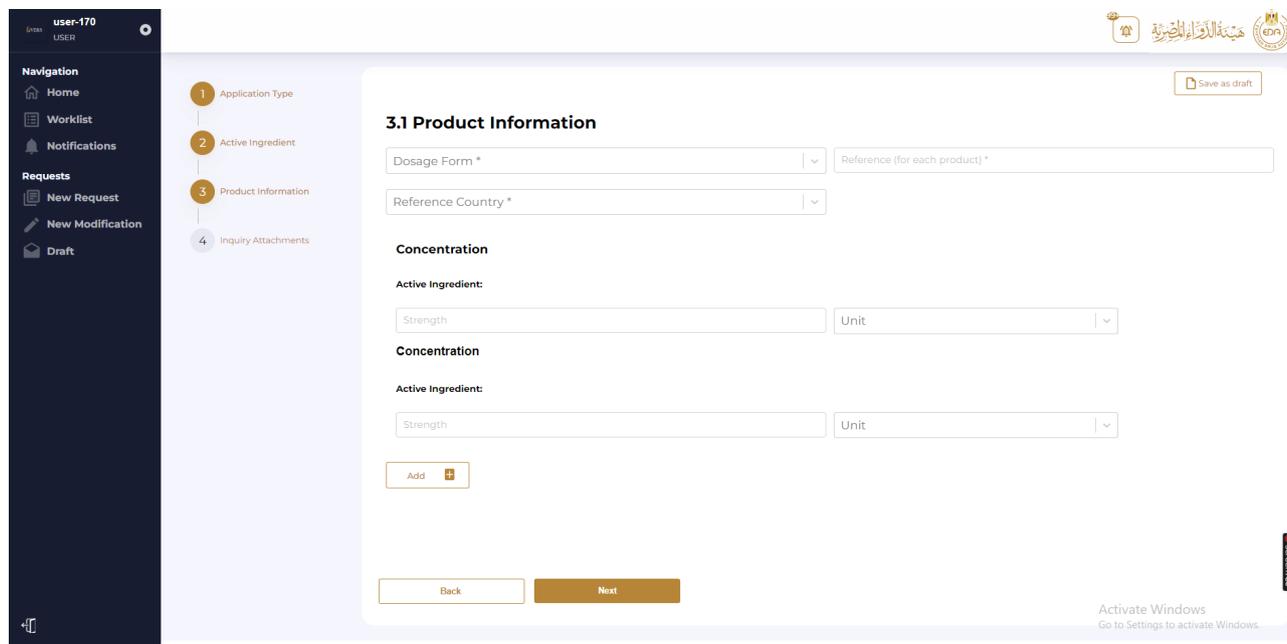


Figure 2.16: Product information

The product information like the dosage form, reference country, concentration, etc associated with each active ingredient. For each active ingredient there should be a corresponding product information

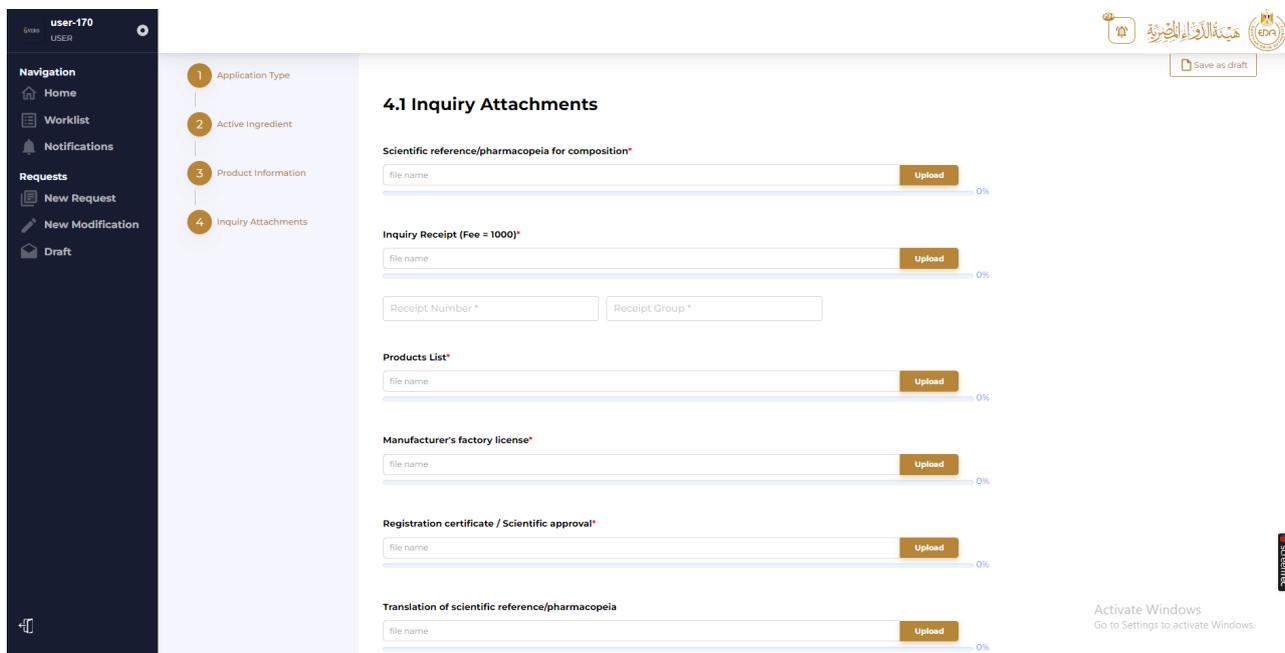


Figure 2.17: Inquiry attachments

After filling all the data and pressing next the user will be asked to upload a list of files some of them are mandatory and some are optional as shown.

The company should only upload PDF files, other types of files will be rejected by the portal and this message should appear "please check files extensions". Also, encrypted PDF files won't be accepted.

The company can use the multiple uploads feature. This means the company can upload more than one file under each attachment request. There is a difference between the multiple upload feature and the single upload feature. Multiple uploads feature does not have a load bar, while the single upload feature has a load bar. Moreover, the button for multiple upload feature says "Upload Files", while the single upload feature says "Upload".

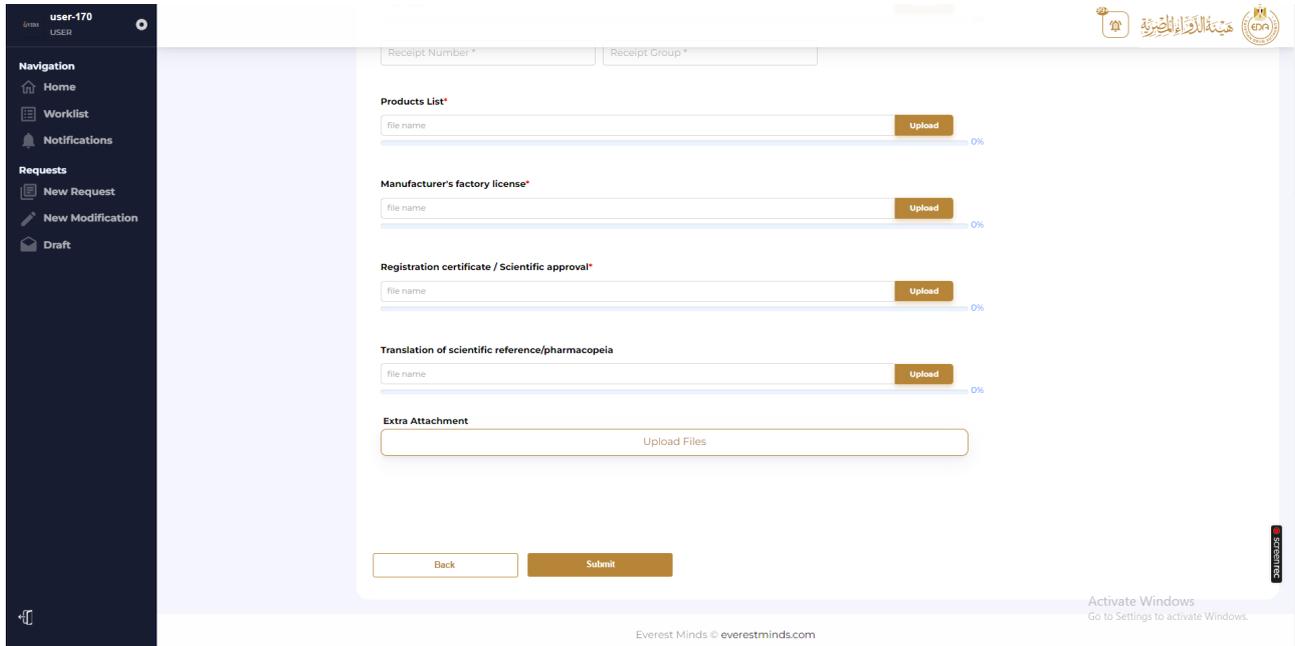


Figure 2.18: Extra attachments

Extra attachments option is available. If the company uploaded all the required attachments and also wanted to attach more PDF files to the submission.

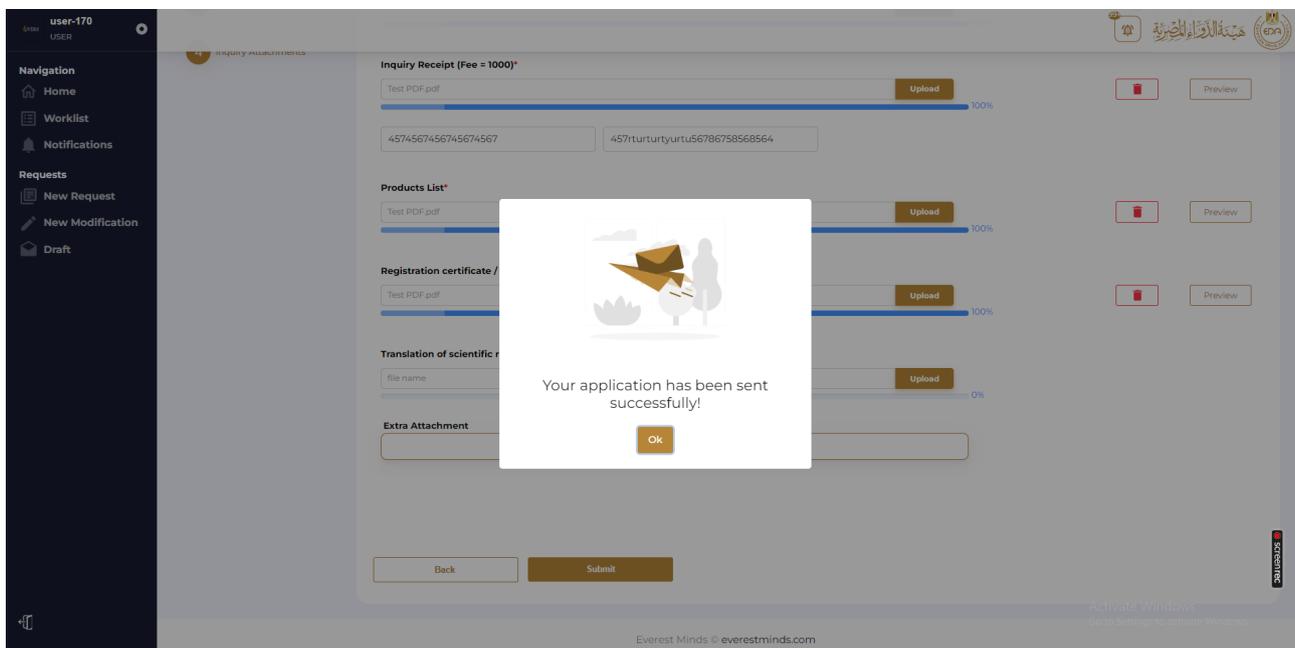


Figure 2.19: Submit message

After the company entered all the mandatory data and uploaded all the obligatory PDF files. There is a message ensuring that you filled all the mandatory fields successfully.

The contents of this document and any attachments are confidential and are intended solely for the use of the individual or entity to whom they are addressed.

2.1.5 Draft

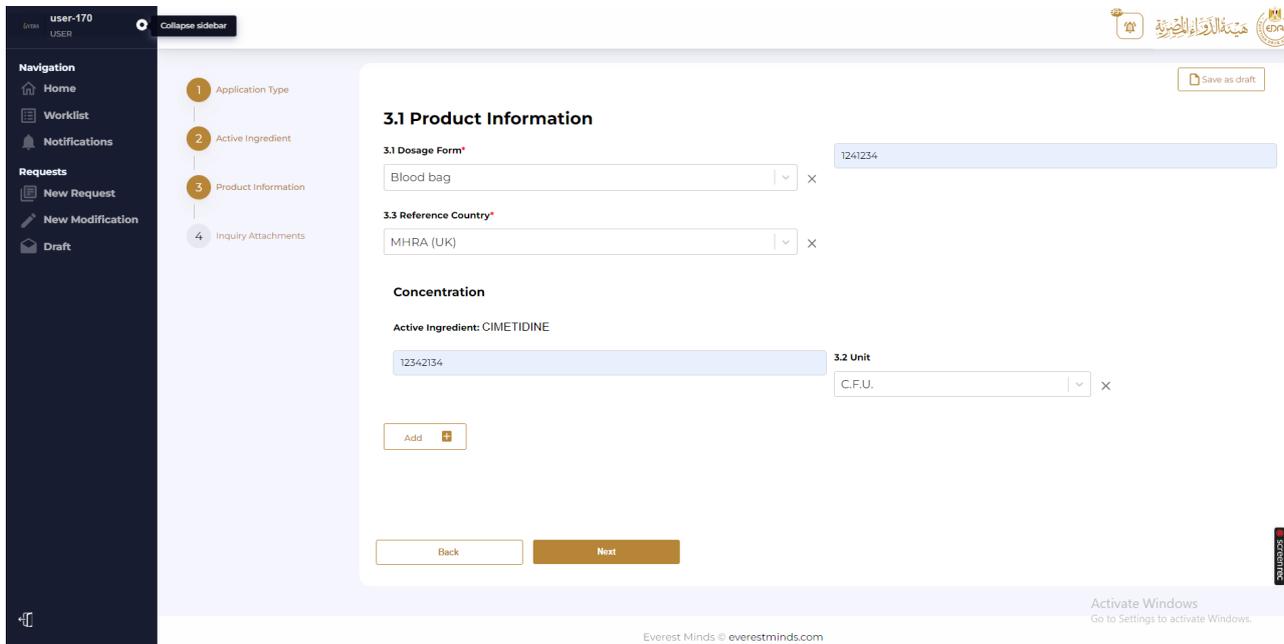


Figure 2.20: Draft

While filling the application the user will have the ability to save the application as a draft from the button at the top right corner “Save As Draft”

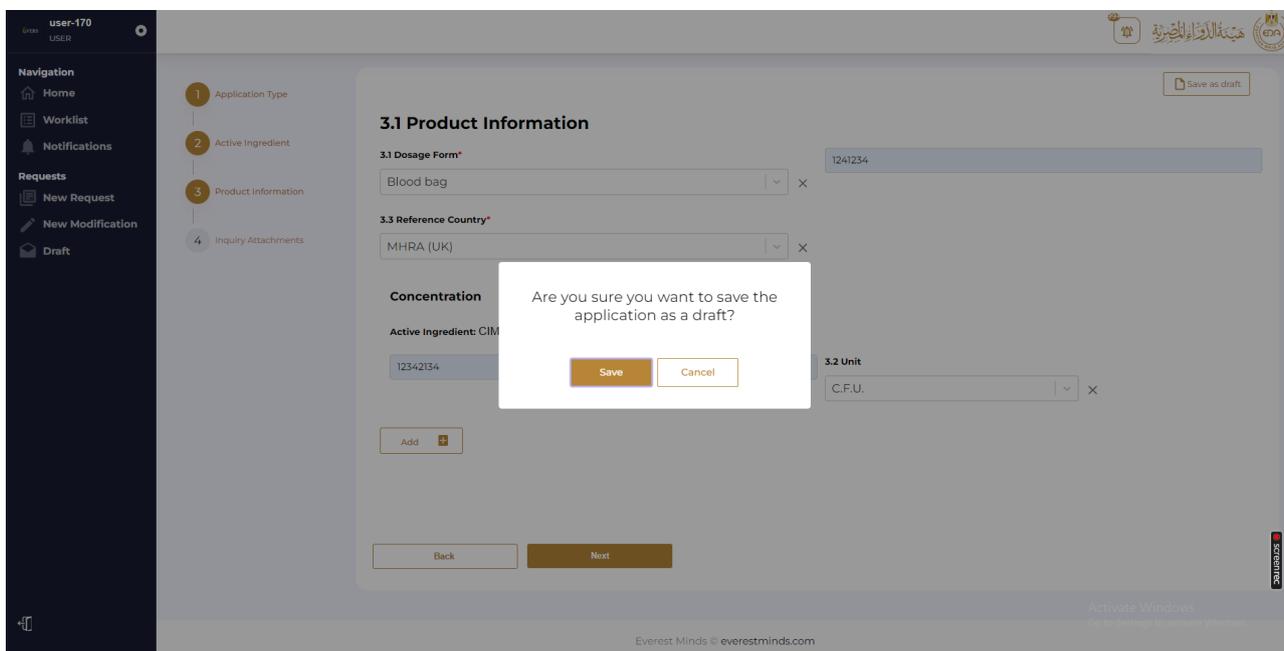


Figure 2.21: Draft 1

The user will then be asked to confirm his choice and press save as shown.

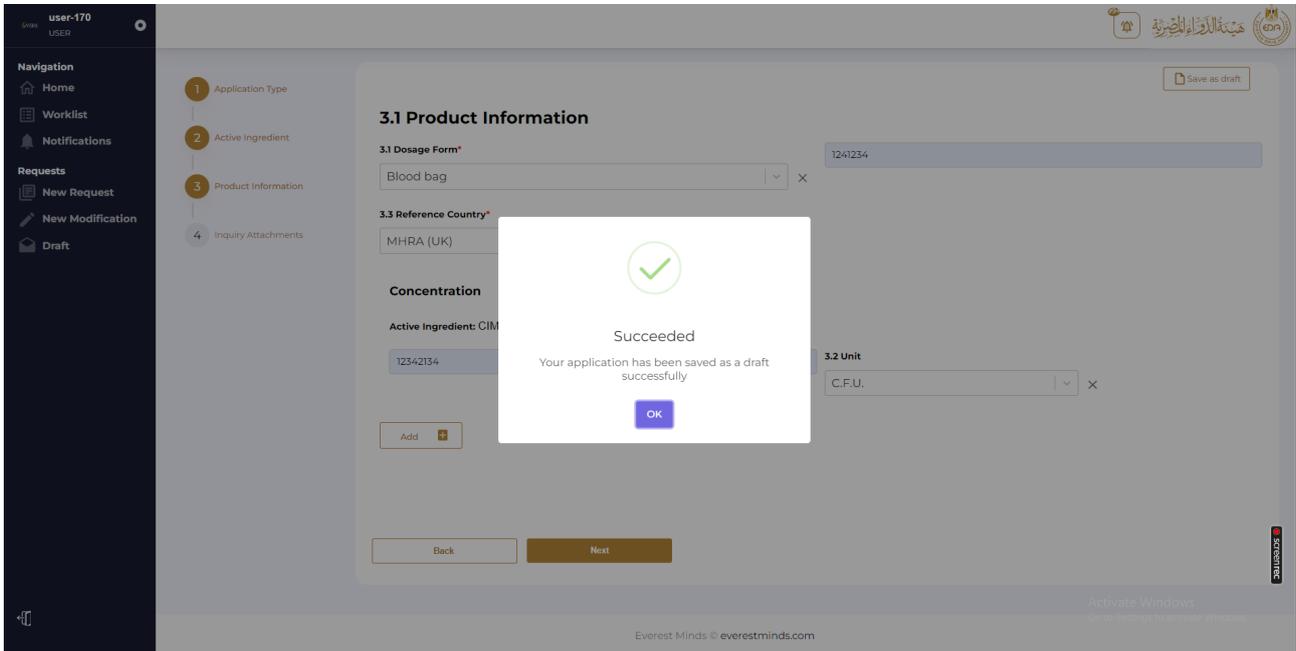


Figure 2.22: Save as draft successfully

The submission should be saved as draft for the company to resume working on it.

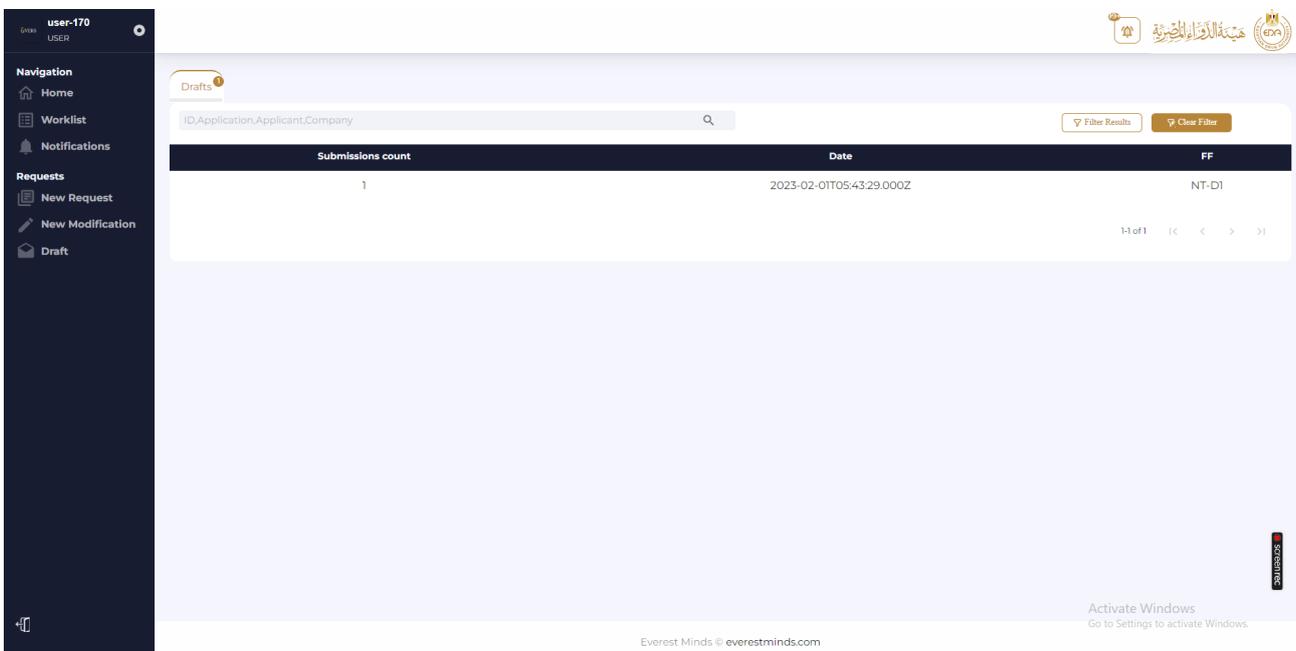


Figure 2.23: Save as draft successfully

The company can find the saved as draft submission by clicking on the "Draft" section in the navigation side bar.

2.1.6 Submission Details page

Once the user submits his application he can then find it inside the ongoing tab, and he can press on it to open the submission details page.

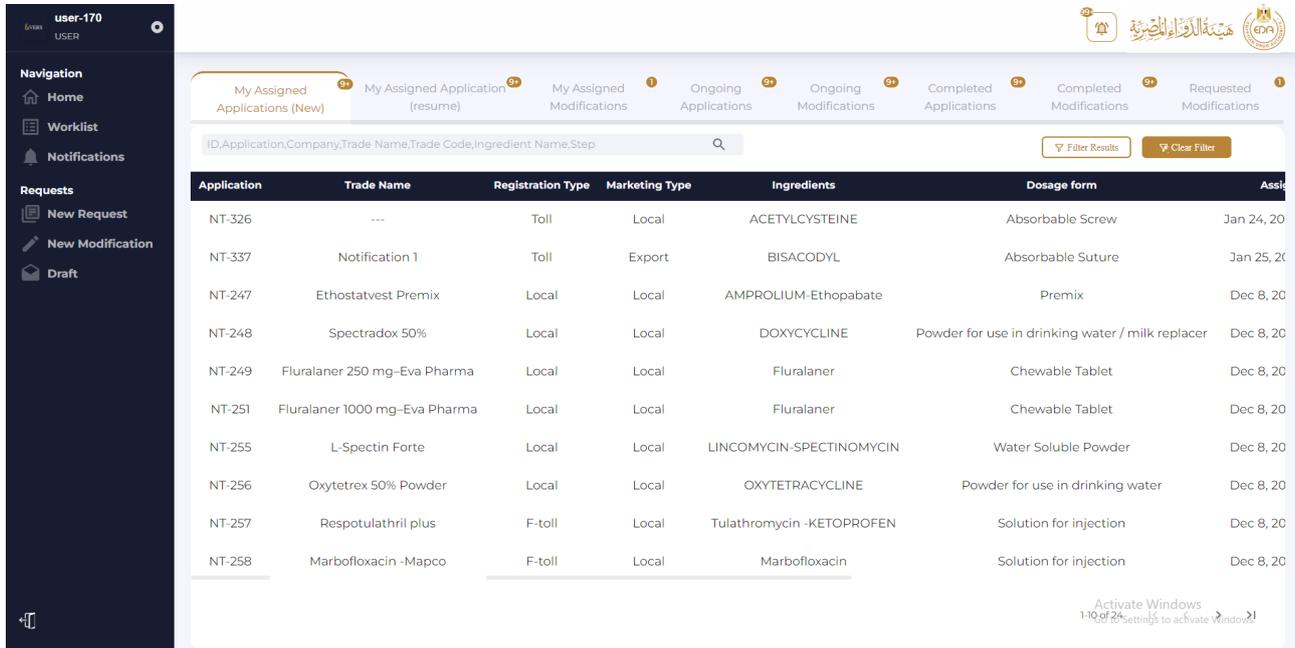


Figure 2.24: Work-list page

The submission details page will contain more than one tab each containing different types of data regarding the application. These tabs are as follows:

Product Details

The Product Details page contains the submission details

Product Details

- Inquiry Request Check List
- Naming Files
- Soft Files Check List
- Hard Files Check List
- Modifications
- Final approval

1. Product Details

1.1 Application Type

Type Of Marketing	Export
Line Extension	true
Type Of Registration	Local
Accepted Name	EISamman's Demo for manual
Still Under Construction	Yes
Company Name	vetopharm nerhado international for pharmaceuticals and chemicals
Contact Email	registration@vetopharm-eg.com
Manufacturer Name	15 MAY PHARMACEUTICAL (M.P.C)-EGYPT

Product Information

Dosage Form	Ampoule
Reference (for each product)	2345235234
Reference Country	TGA (Australia)

1. Ingredients

Active Ingredient	HYDROCORTISONE
Unit/Strength	12342134 billion

1. Salts

Figure 2.25: Product details page

Inquiry request Checklist

Inquiry request Checklist contains the Inquiry documents uploaded by the company.

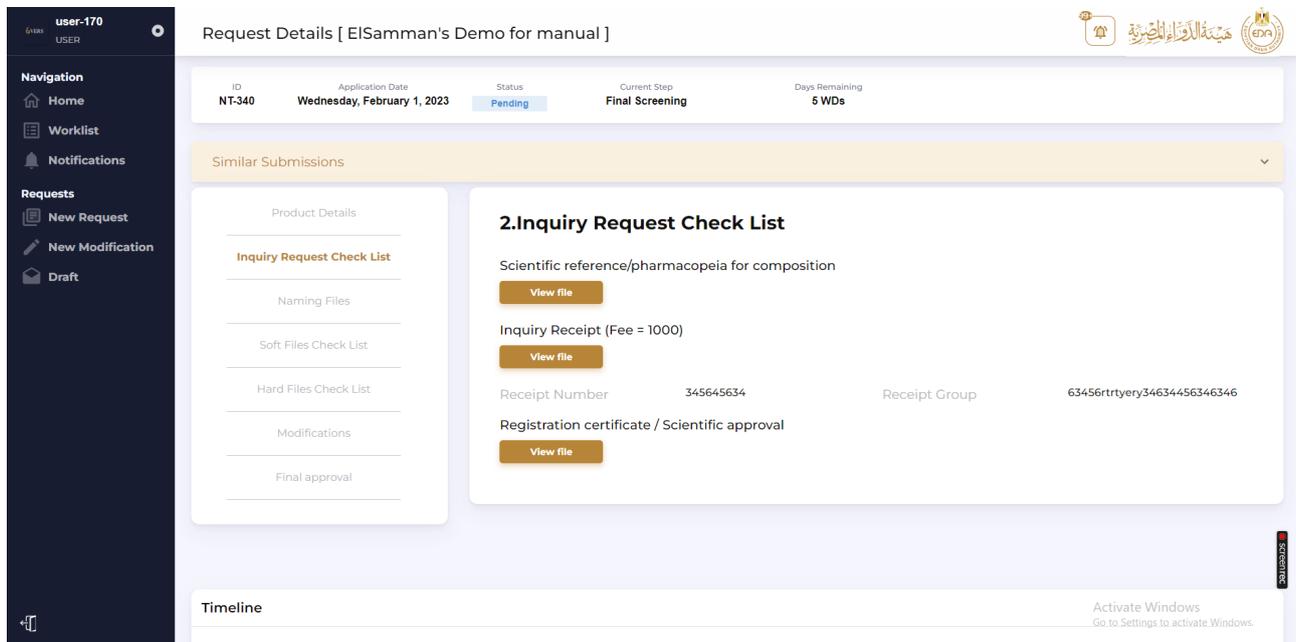


Figure 2.26: Inquiry request Checklist

Naming files

This is the files that is submitted during the naming process

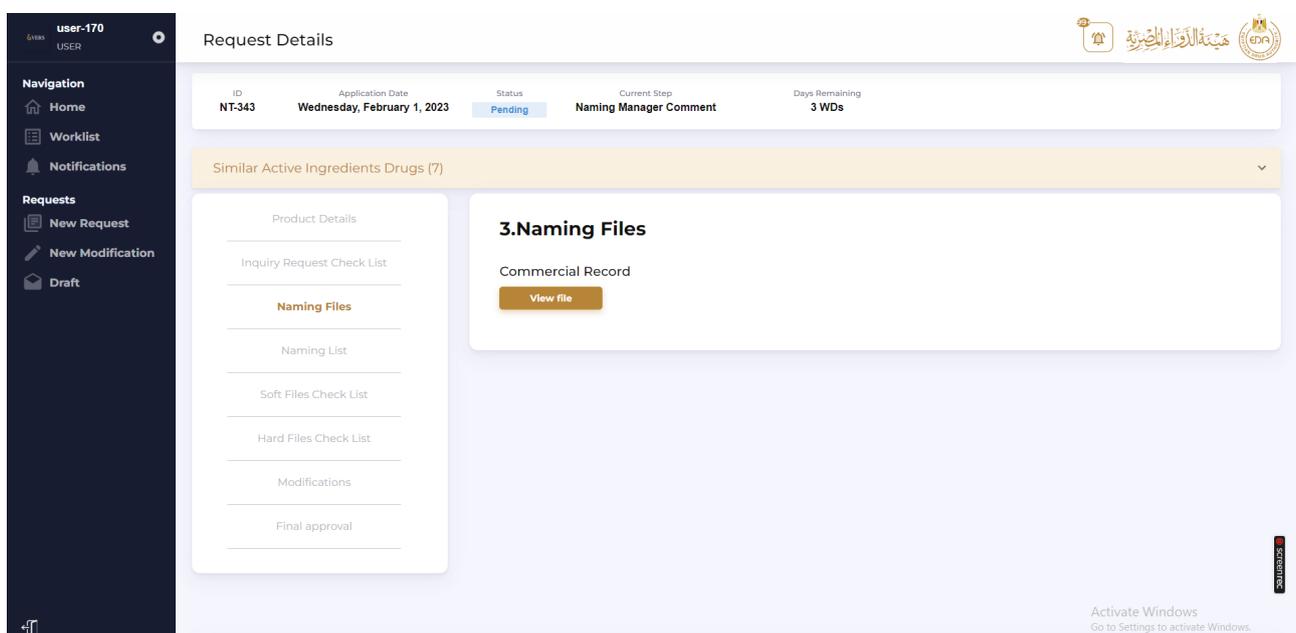


Figure 2.27: Naming files

Naming List

This is list of names submitted during the naming process

Name Order	Proposed Name	Arabic Name	Voice Note
1	kaskhg-vetopharm nerhado international for pharmaceuticals and chemicals	كاسكج	
2	asdfsdfsadf	اسدفسد	
3	asdfsdfdf	اسدفسد	
4	sadfsaddfdf	اسدفسد	

Figure 2.28: Naming List

Soft files checklist

The Soft files checklist are the documents uploaded by the company during the soft file process

Document Type	View file
Preliminary Scientific Data Report	View file
Soft Files Receipt	View file
Receipt Number	124124231241234
Receipt Group	412312412341234234uy34y34
Supporting Document	View file
Additional Reference	View file
Additional Reference	View file
Additional Reference	View file

Figure 2.29: Soft files checklist

Hard files Checklist

The Hard files checklist are the documents uploaded by the company during the hard file process

Request Details [Ethostatvest Premix]

ID: NT-247 | Application Date: Thursday, December 8, 2022 | Status: Pending | Current Step: junior hf | Days Remaining: 10 Ds

7. Hard Files Check List

- Certificate of Veterinary Products [View file](#)
- Scientific Committee Approval [View file](#)
- Central Administration for Drug Control Report (NODCAR report) [View file](#)
- General Administration of Stability Report [View file](#)
- Hard Files Fees Mandatory [View file](#)

Receipt Number: 457457755454545455 | Receipt Group: 567456745457454574575rt

Formulation Composition [View file](#)

Figure 2.30: Hard files checklist

Modifications

This list of modifications the company applied for regarding any of its submissions

Request Details [Ethostatvest Premix]

ID: NT-247 | Application Date: Thursday, December 8, 2022 | Status: Pending | Current Step: junior hf | Days Remaining: 10 Ds

4. Modifications

- Change of Manufacturer / license holder -after scientific committee approval done 04/01/2023 Accepted
- Issues for scientific committee opinion 11/01/2023 Rejected
- Issues for scientific committee opinion 11/01/2023 Accepted

Figure 2.31: Modifications

2.1.7 Final approval

In this section the company can find all the final approvals

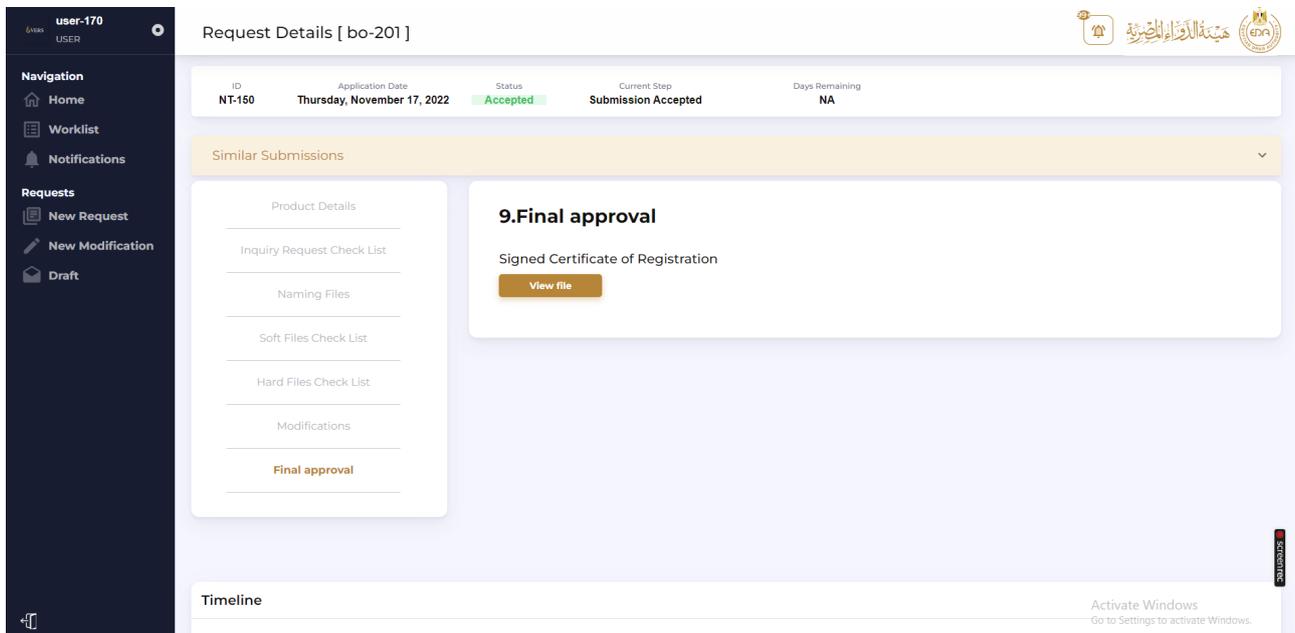


Figure 2.32: Final approval

The company can find the comments sent to them in the comments section showing the date of the comment and who sent it and in which step was it sent along with an attachment if any.

2.2 Re-uploading Documents

At any time during the process the submission can be sent back to the company to re-upload the unaccepted documents

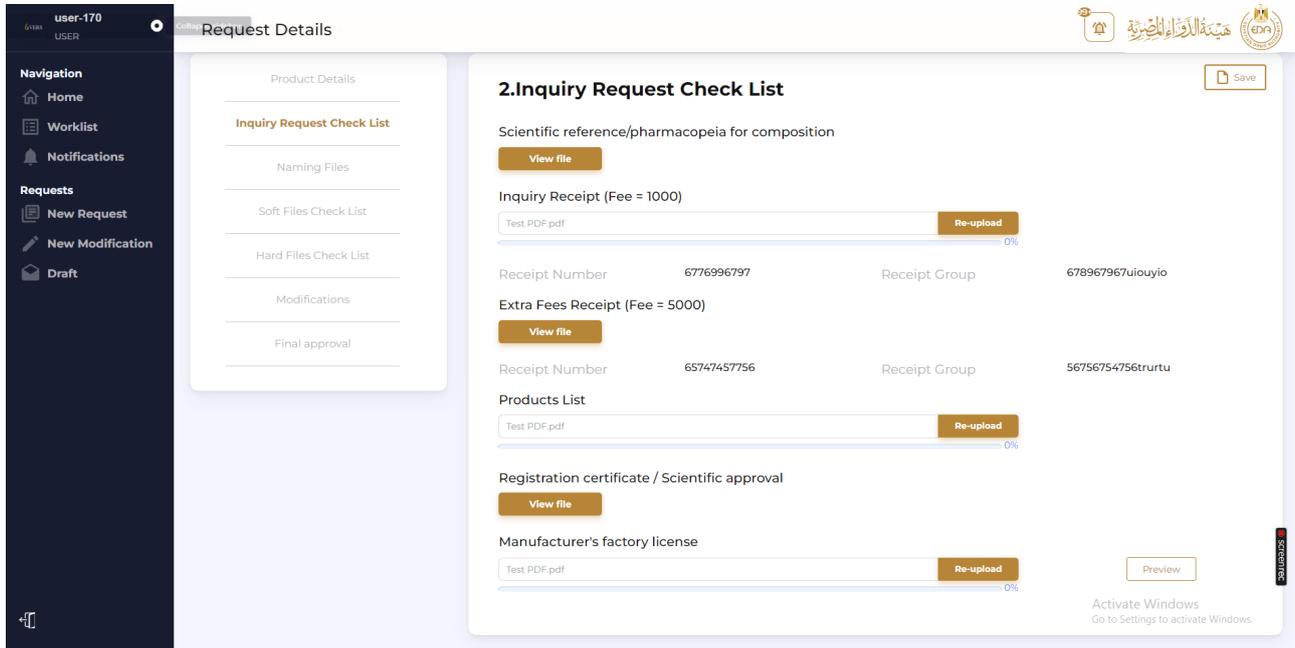


Figure 2.33: Re-uploading documents

The company will be able to open the submission from their work list “My Assigned Applications Tab” or from the notification they received to open the submission details page from which they will be able to access all their submission details and re-upload the required documents.

The company will then have to re-upload the required documents by opening the Checklist Tab on the navigation bar inside the details page and start re-uploading all the documents.

After uploading all the documents the user should make sure to press on the save button on the top right to confirm his new uploads.

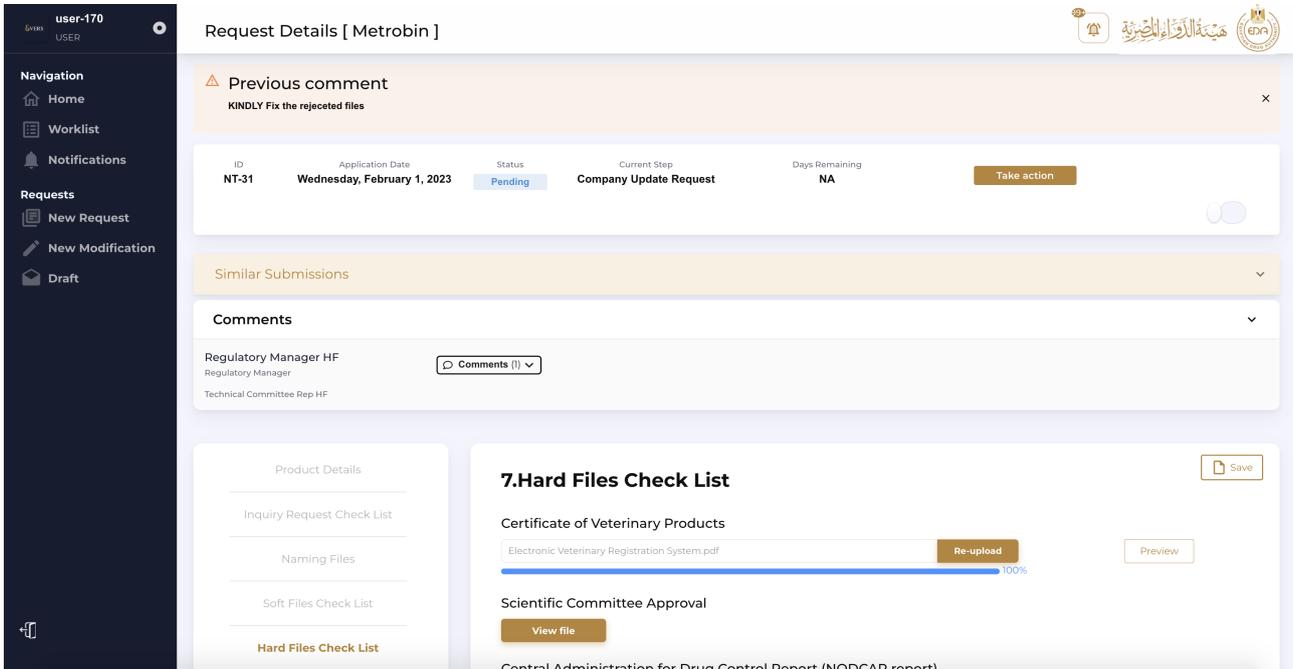


Figure 2.34: Take action enabled

The take action button on the top corner inside the details page will now be enabled.

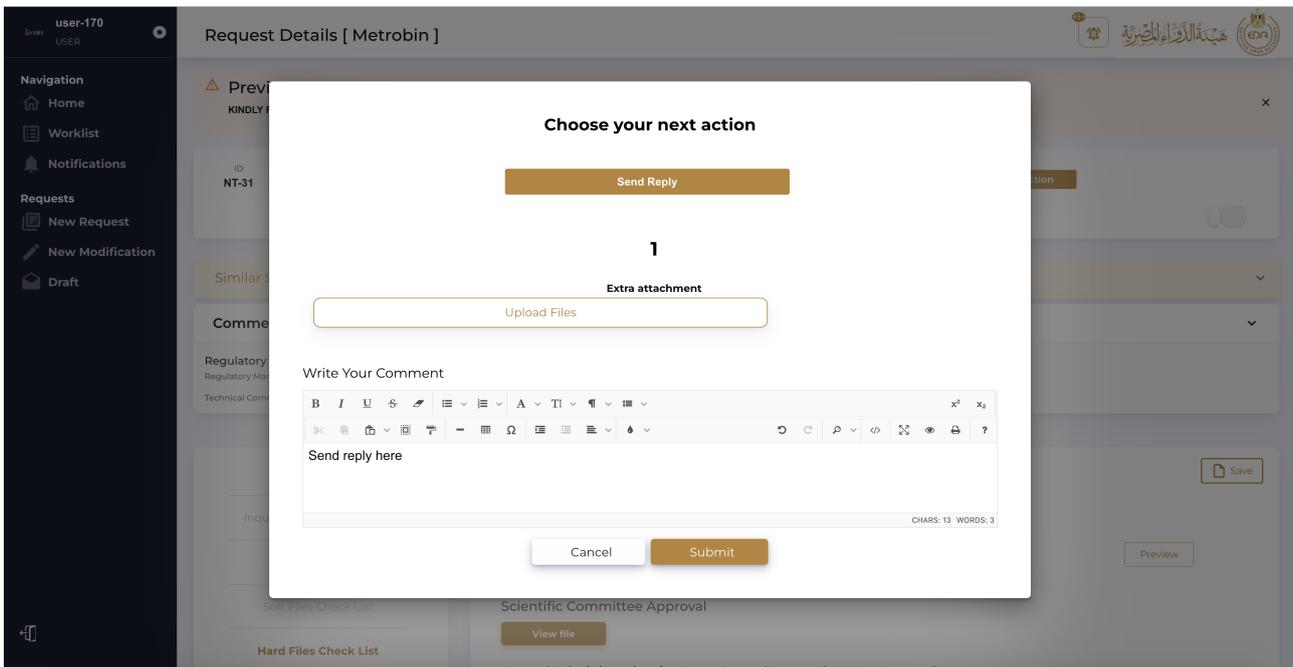


Figure 2.35: Taking action

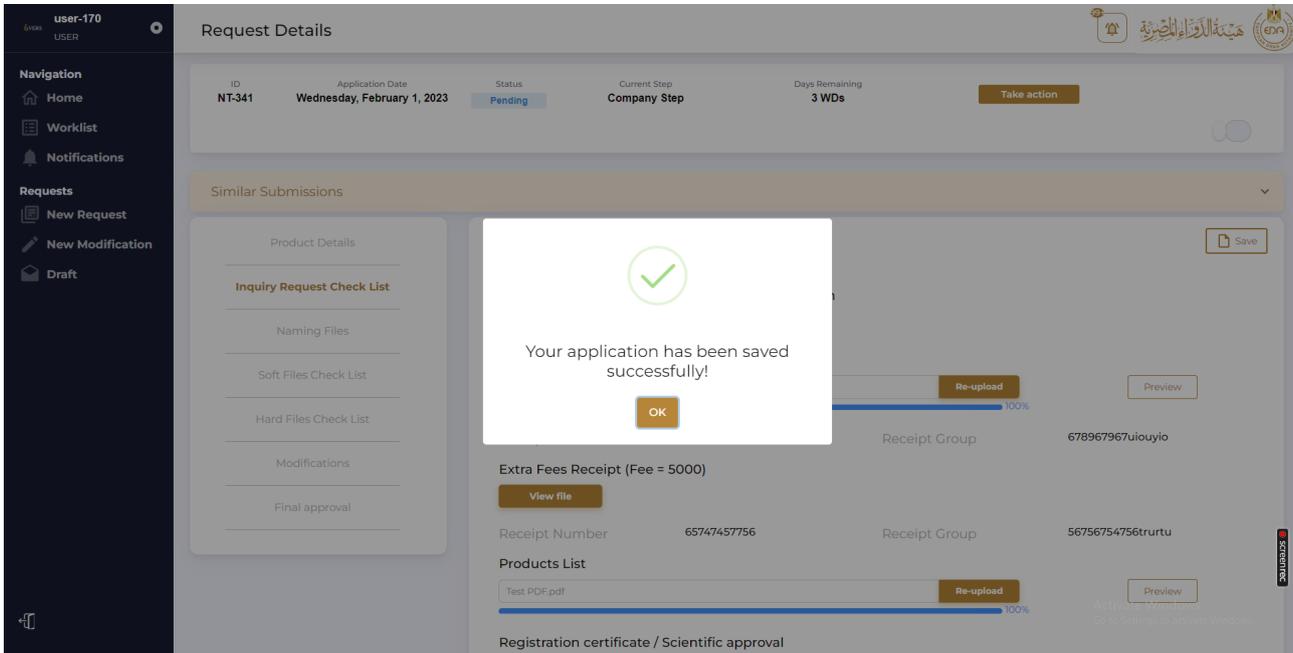


Figure 2.36: Action Taken

The company is now able to press on the “Take Action Button” to Re-forward their submission again to the EDA; they will also be given an option to upload any extra attachment or send a comment if needed.

By pressing submit the application will be sent once again to the EDA to continue assessment.

2.3 Naming process

2.3.1 Line extension

Figure 2.37: Line extension form

2.3.2 Normal name list

Figure 2.38: Normal name list form

Drug Type	Drug Name	Arabic Drug Name	Name Order	Similarity	Acceptance	Recording
Generic	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			

Figure 2.39: Normal name list form

Drug Type	Drug Name	Arabic Drug Name	Name Order	Similarity	Acceptance	Recording
Generic	<input type="text" value="asdfsd"/>	<input type="text" value="تشدشش"/>	<input type="text" value="2"/>			
Company name position: <input checked="" type="radio"/> Beside drug name <input type="radio"/> Below drug name						
Trade Name	<input type="text" value="qwqwersdf"/>	<input type="text" value="مستخلص"/>	<input type="text" value="1"/>	47%	Initial Acceptance	
Trade Name	<input type="text" value="qwesdfasdf"/>	<input type="text" value="تشدشش"/>	<input type="text" value="5"/>	50%	Initial Acceptance	
Trade Name	<input type="text" value="pandol"/>	<input type="text" value="مستخلص"/>	<input type="text" value="4"/>	74%	Initial Rejection	
Trade Name	<input type="text" value="asdfsdfqwer"/>	<input type="text" value="تشدشش"/>	<input type="text" value="3"/>	55%	Initial Acceptance	
Trade Name	<input type="text" value="sdfsdfsawerqewrtyuy"/>	<input type="text" value="مستخلص"/>	<input type="text" value="6"/>	51%	Initial Acceptance	
Trade Name	<input type="text" value="Drug Name"/>	<input type="text" value="Arabic Drug Name"/>	<input type="text" value="Narr"/>			

Figure 2.40: Normal name list form

2.4 Start soft file

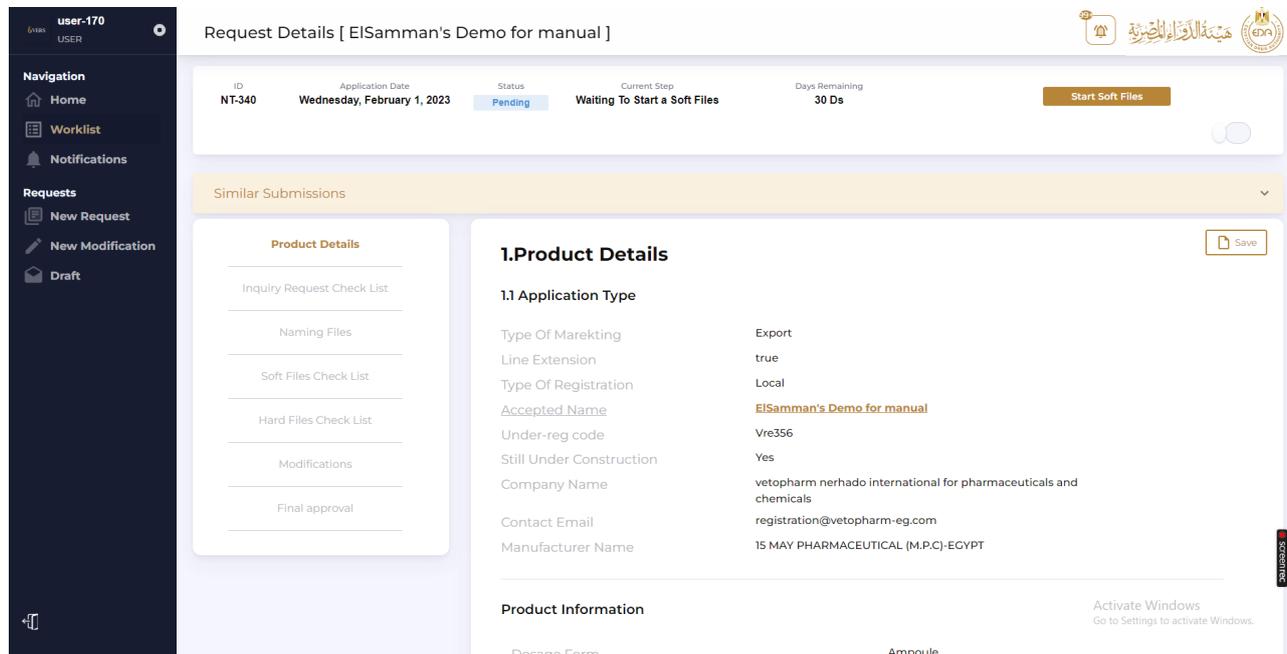


Figure 2.41: Waiting to start soft file

To start Soft Files Process you will be asked to upload a checklist of files according to your registration type and submit it to the EDA

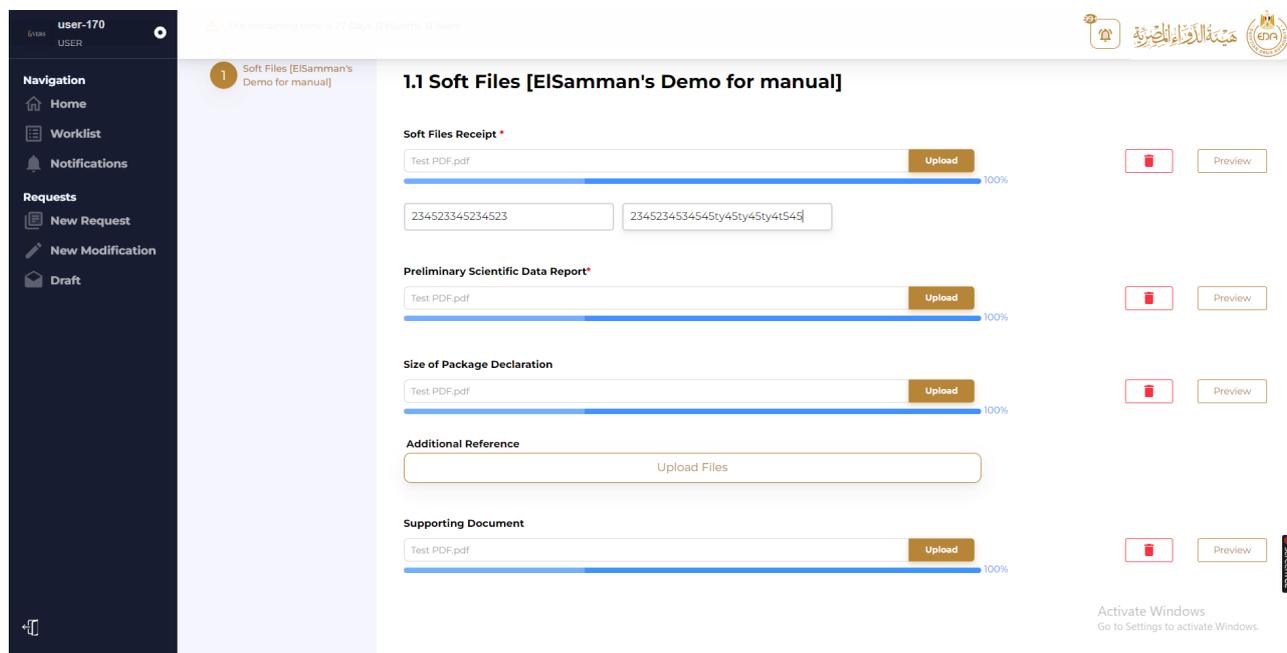


Figure 2.42: Uploading the soft files

2.5 Start hard file

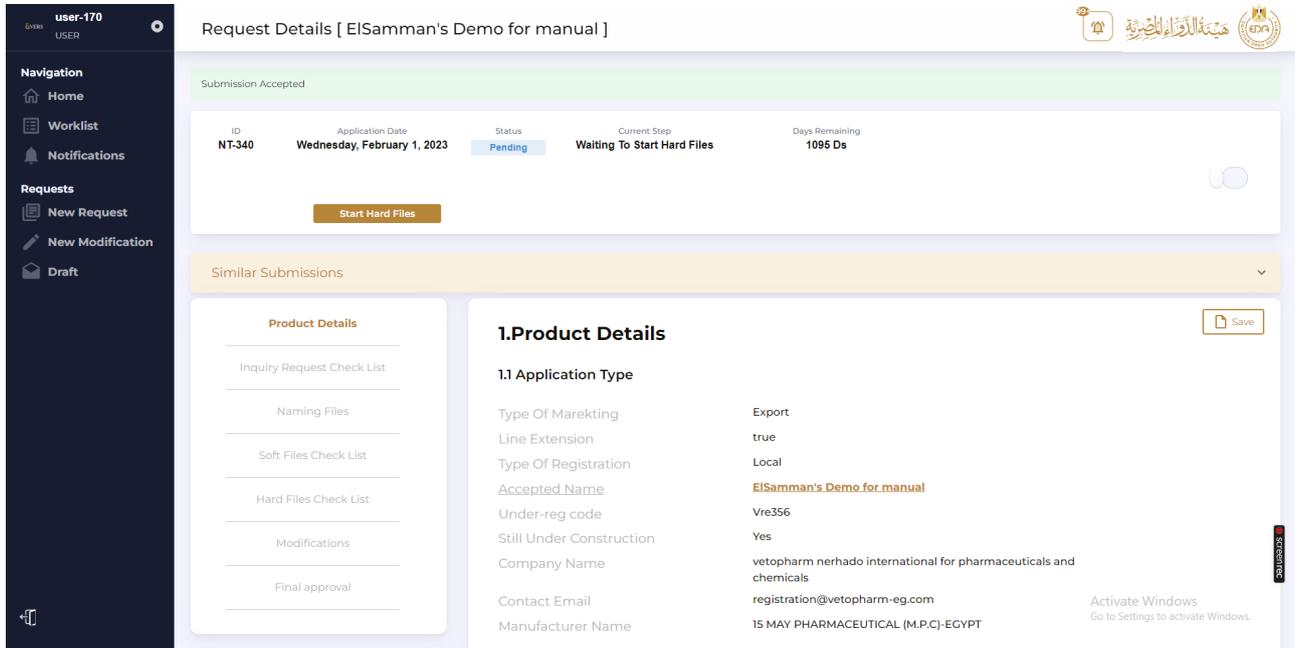


Figure 2.43: Waiting to start hard file

To start Hard Files Process you will be asked to upload a checklist of files according to your registration type and submit it to the EDA

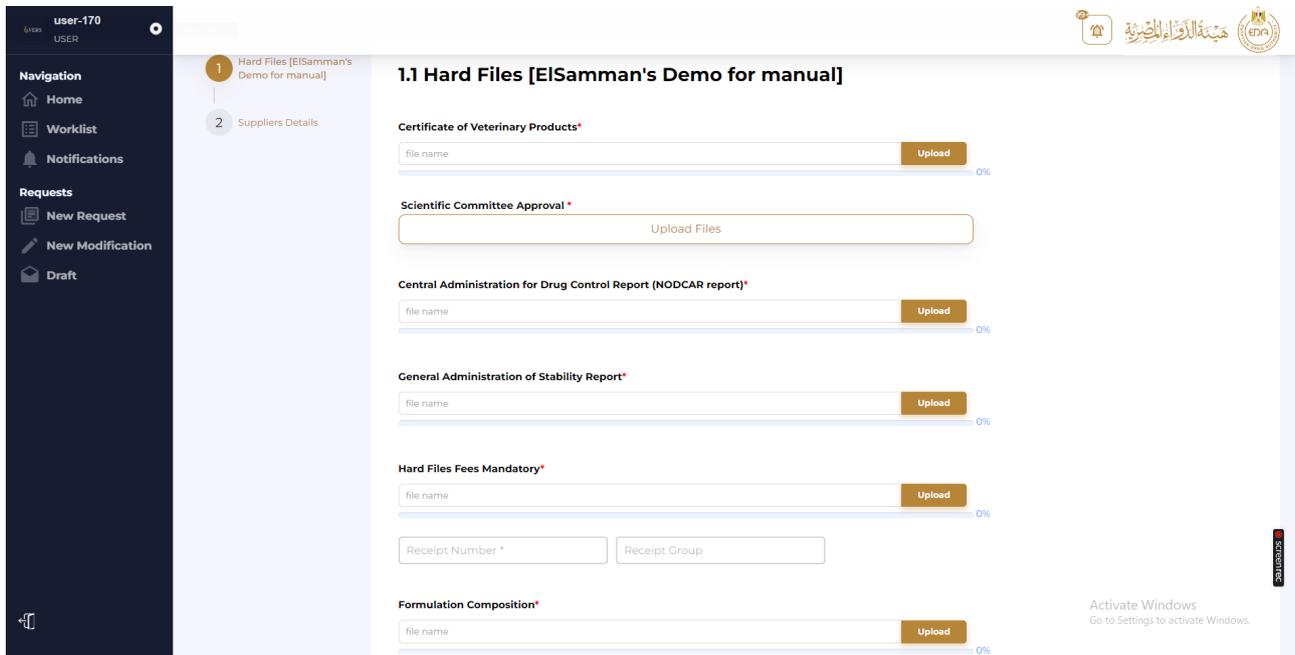


Figure 2.44: Uploading the hard files

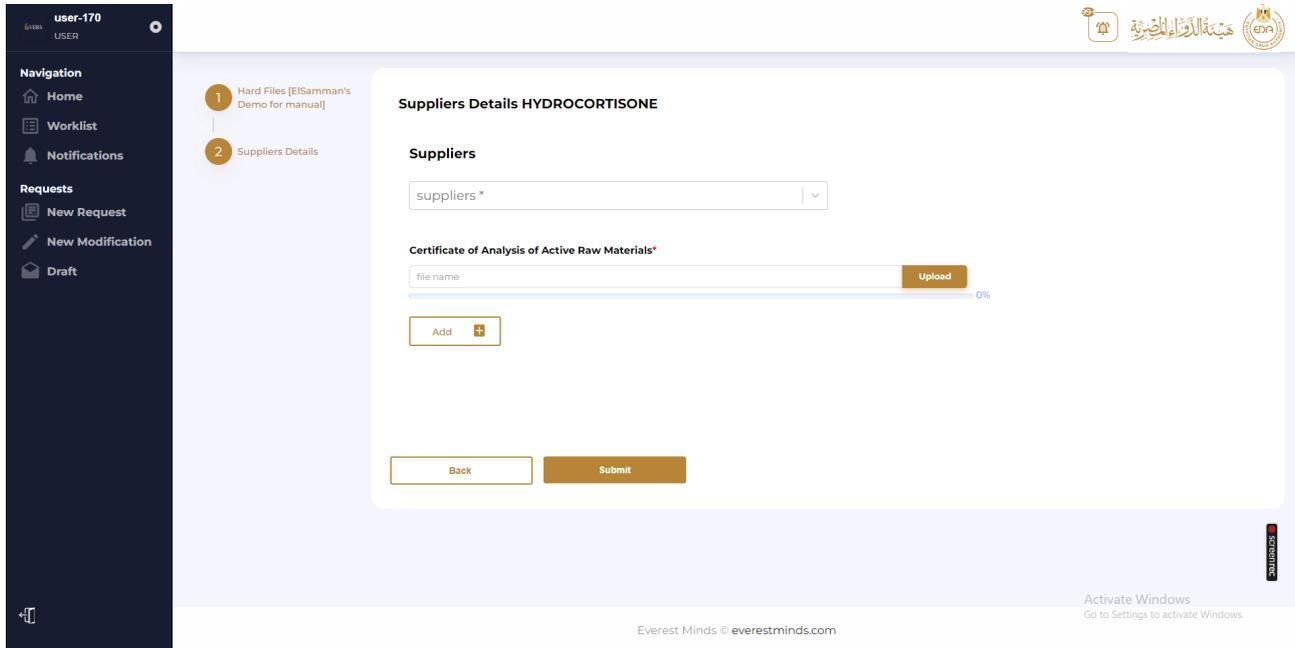


Figure 2.45: Uploading the suppliers details

2.6 Modifications

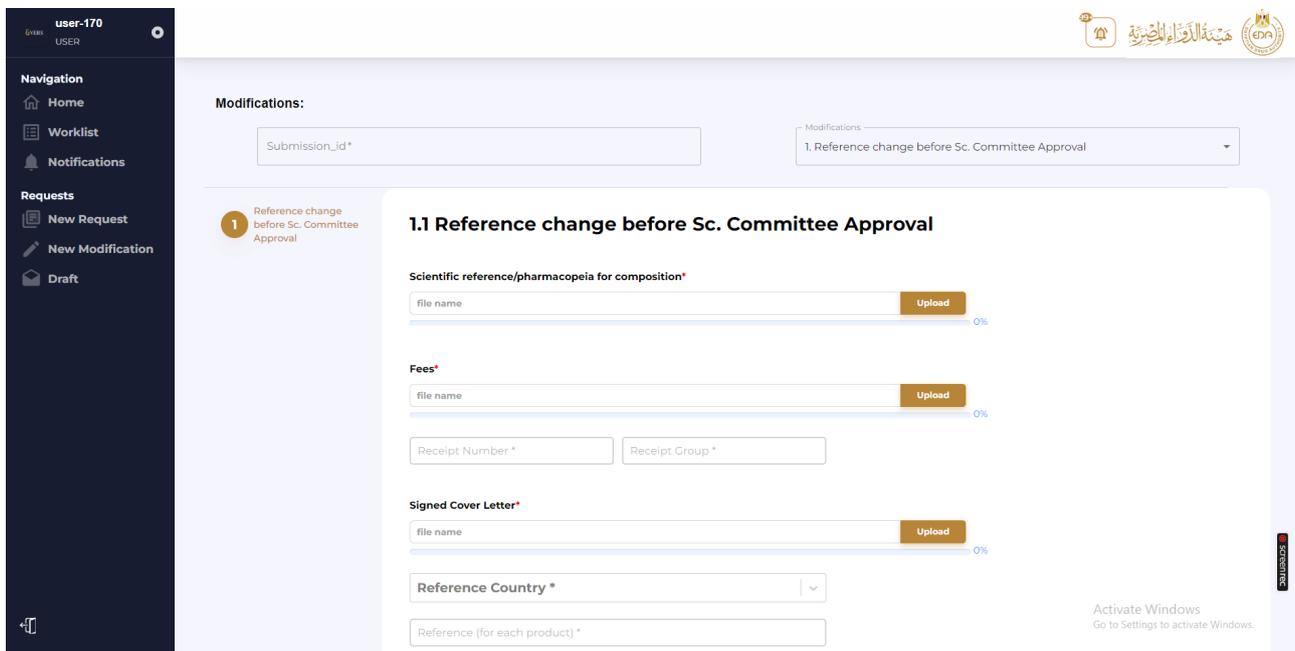


Figure 2.46: Applying for a modification

The user can apply for a modification through the modification section in the side navigation bar. Firstly the user should select the modification that he/she wish to request. Then the user should make sure that the submission ID is correct.

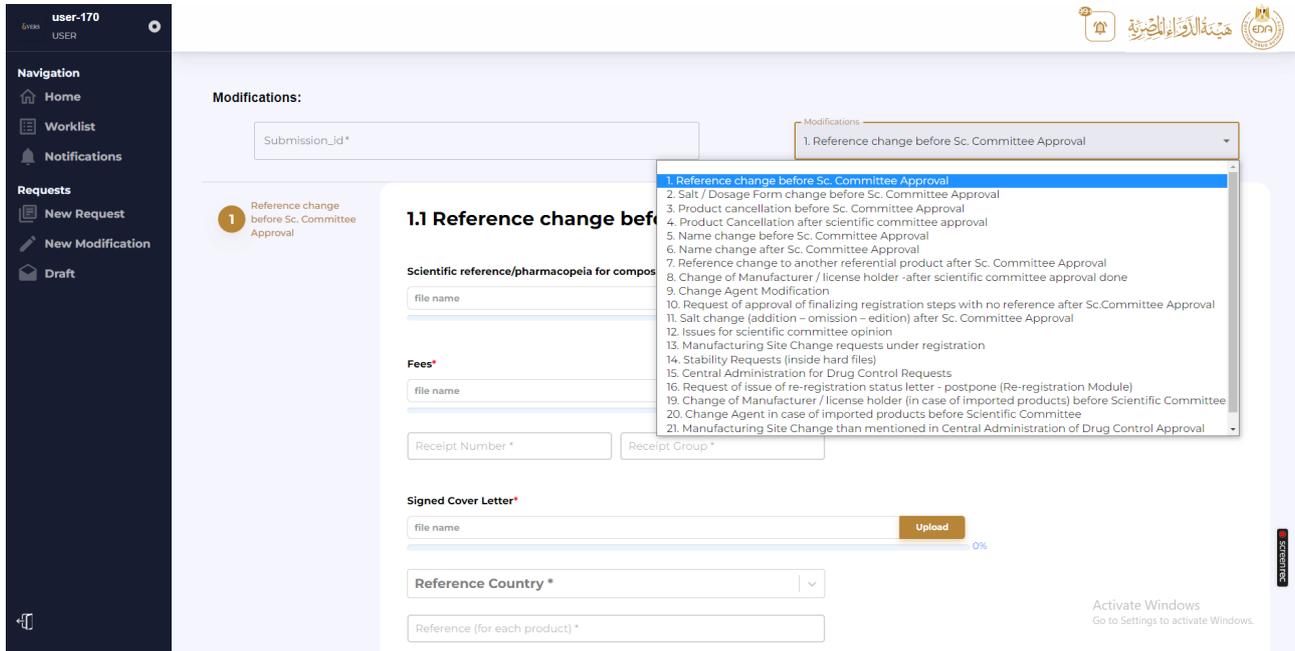


Figure 2.47: Applying for a modification

For any modification request the following points should be considered:

- The user requesting the modification should enter the Submission request id to proceed with the request.
- Only One modification can be requested at the same time for each request.
- Once the user applies for a modification request, all due dates regarding this submission in the normal request are to be put on hold and no action can be taken on the submission until the end of the modification request.
- After approval of the request all the concerned users will be notified.
- A Modification history on each submission will be available for viewing inside the details page.
- Any modification will require a list of requirements to be filled or uploaded.
- Each modification request has its own workflow and action plan with its own outcomes.

2.7 Status List

This is a table for the each status in the system. This works as a guide to know exactly the status of the application.

Status Name	Description
Pending	This means the submission is under processes
Queue	This means your submission is inside a Queue and waiting for its turn for the EDA to start working on
Modification	This means your submission is under a modification process
Rejected/Cancelled	This means the submission is rejected or cancelled by the EDA
Accepted	This Means the submission has ended and you got your Certificate of Registration

2.7.1 Screenshots for the status names

ID	Application Date	Status	Current Step	Days Remaining
NT-269	Saturday, December 10, 2022	Rejected	Submission Rejected	NA

Figure 2.48: Rejected status

ID	Application Date	Status	Current Step	Days Remaining
NT-326	Tuesday, January 24, 2023	Pending	Naming List Submission	19 WDs

Figure 2.49: Pending status

ID	Application Date	Status	Current Step
NT-150	Thursday, November 17, 2022	Accepted	Submission Accepted

Figure 2.50: Accepted status

Note : Any Updates on the system resulting in a change in the user manual, an updated user manual will be sent