

Central Administration of Pharmaceutical Products General Administration For Cosmetic Products Registeration

# Cosmetics Companies Portal User Manual 2023

Code: EDREX: NP. CAPP.075

**Version No**: 1

**Issue Date**: 22<sup>nd</sup> March 2023

Effective date: 22<sup>nd</sup> March 2023

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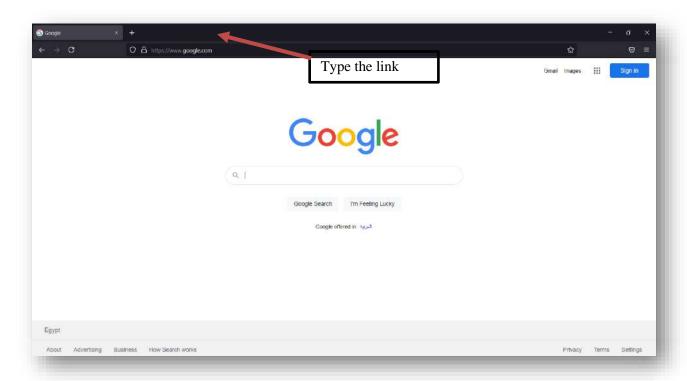
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# 1- Login Screen

# To login the portal, follow these steps:

a) User starts with internet browser prefer (**Mozilla Firefox browser**) then type the link: <a href="https://egycosma.edaegypt.gov.eg">https://egycosma.edaegypt.gov.eg</a>



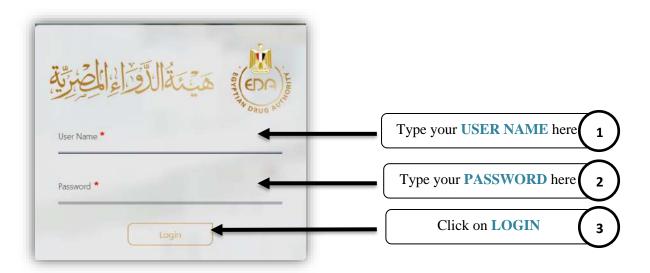
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b) Click enter button to open the login page of portal system as shown in the next picture.



c) Type your pre delivered **user name and password** as shown down.

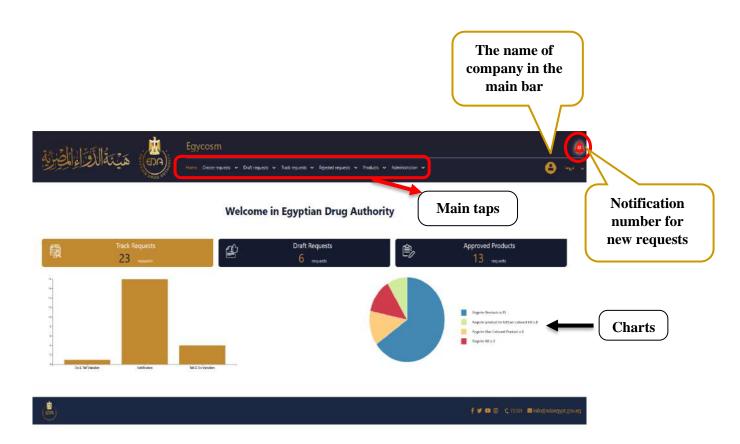


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d) Then you will transfer to the Home page (system interface) as shown in the next page .

# 2- Home Page Screen



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#### **3- Create Request**

# To register a new request, follow these steps:

a) Open Create requests tap from the main tap as shown in the next picture then choose from the drop-down list Notification.



b) Then you will transfer to the page for the Create request for Notification.





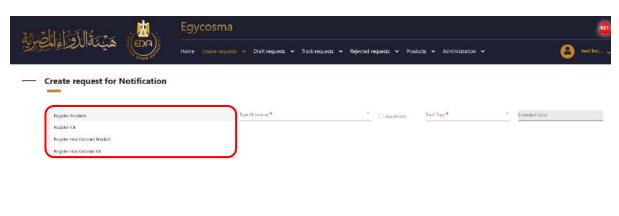
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NOTE: All fields marked with an (\*) are mandatory fields that must be filled, in order for the New Request to be saved and submit.

c) Choose the type of the product that you want to register from the drop-down list **Type of Notification** field.

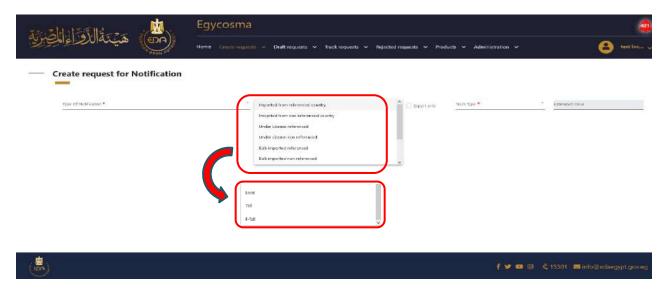




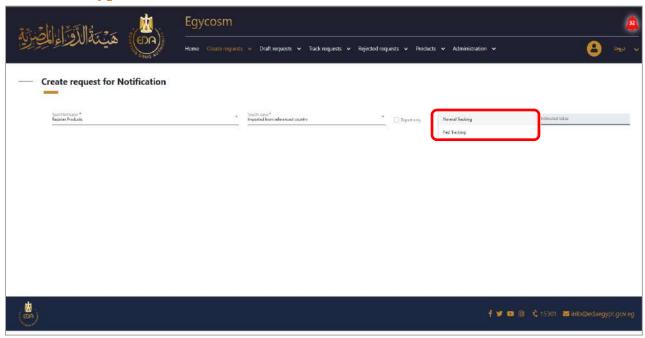
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d) Choose the type of the product license that you want to register it from the drop-down list **Type of License** field.



e) Choose the tracking type for the new product request from the drop-down list **Track Type** field.



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- f) After choosing the type of notification, type of license and track type, the following will appear:
- 1- Estimated fees for this registration in the Estimated Value field.
- 2- All the required details about this registration that depends on the type of notification.

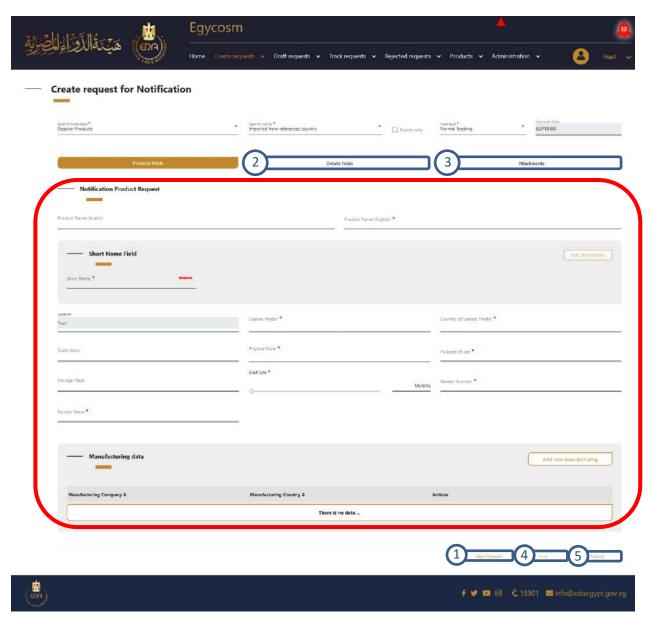
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# \* In case the type of Notification is Register Product



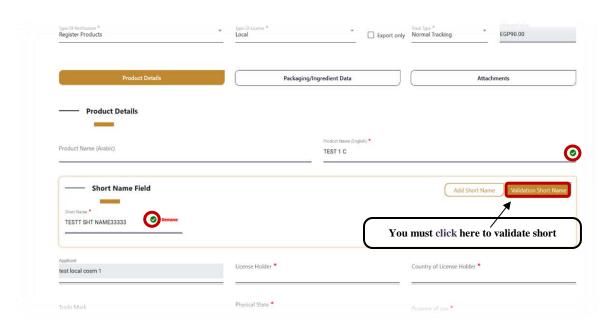
1- The next forward button will transfer you to the next page (1) (details fields) or you can click directly on the details fields (2) tap or on the attachments (3)

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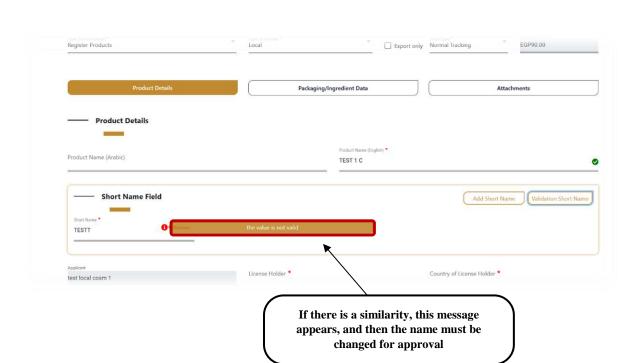
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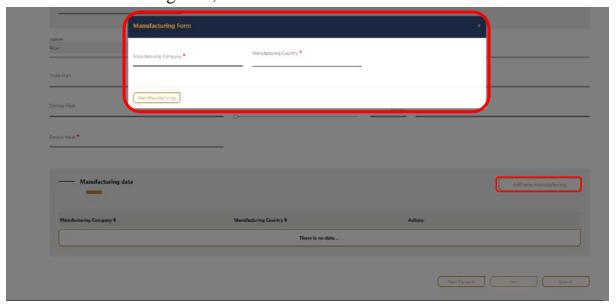
- 2- After filling at least one field with its custom data the save button (4) will be activated and the request will be saved in **draft requests menu > notification tap** until you complete all mandatory fields which have small red star on it (\*) in the Type of Notification page, Type of license page and Track type page you can able to submit by clicking on submit button (5) and the request will transfer to **track requests menu > notification tap**.
- 3- When entering English name and short name There is a matching process that happens to the names, and in the event that there are similarities in the names, the name must be change to be approved



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4- Click on add new manufacturing then a pop-up will appear including the form of manufacturing data, consists of:



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5- You must save the product and it will go directly to **Draft requests** 

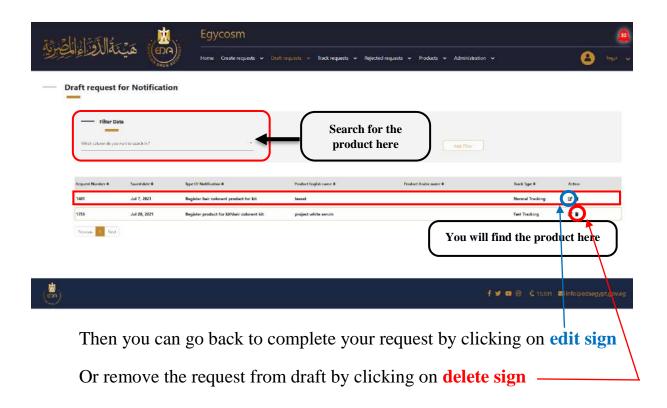
In order to make sure that the product has been saved and return to complete it again in anticipation of any technical malfunction



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# **Draft requests > Notification page**



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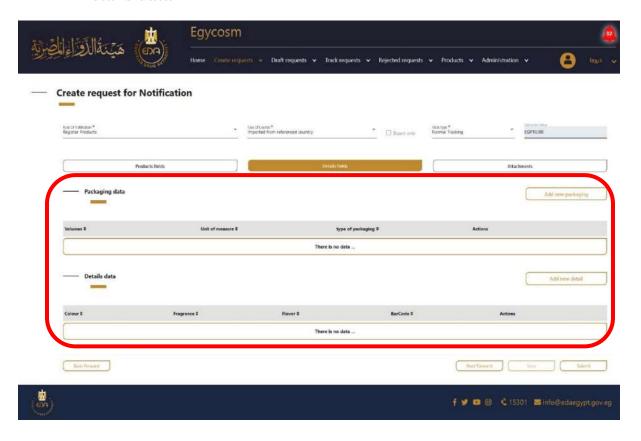
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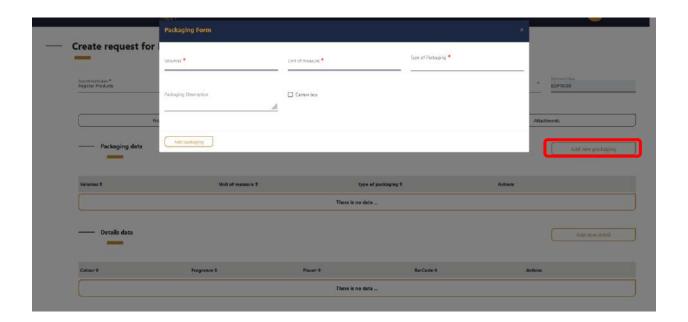
❖ The tap of Details fields is divided into two parts: Packaging data,
Details data



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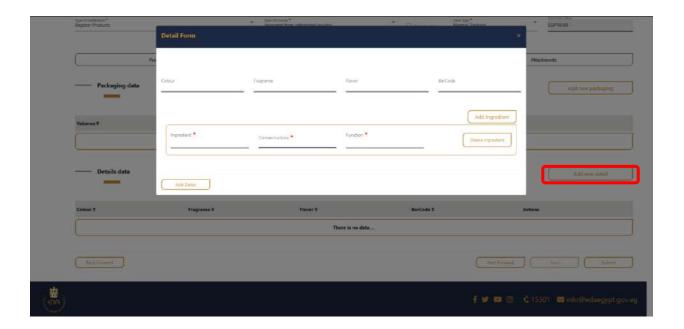
Click on add new add new packaging then a pop-up will appears including the form of packaging data, consists of:



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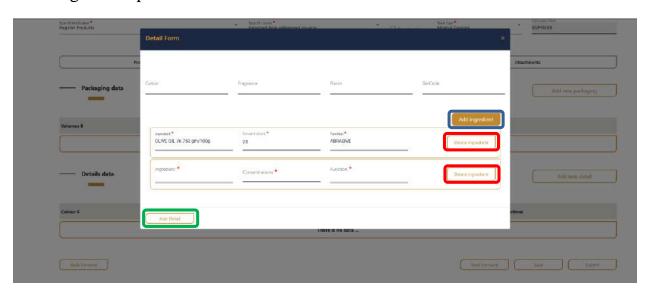
Click on add new detail then a pop-up will appears including the form of details data, Consists of:

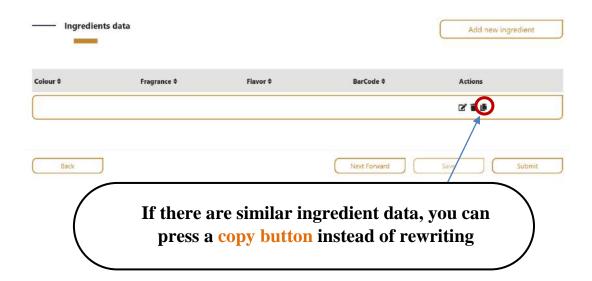


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You can add many ingredients or delete them from those buttons and after finishing this step click on add details button



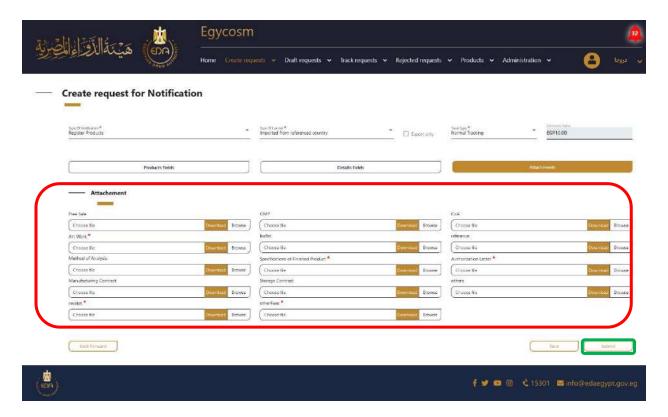


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Here you add all the documents related to the product, each in the place designated for it in the tap of **attachments** (must be pdf)



At the end you make sure that all the mandatories fields are filled with its custom data then click on **Submit button** 

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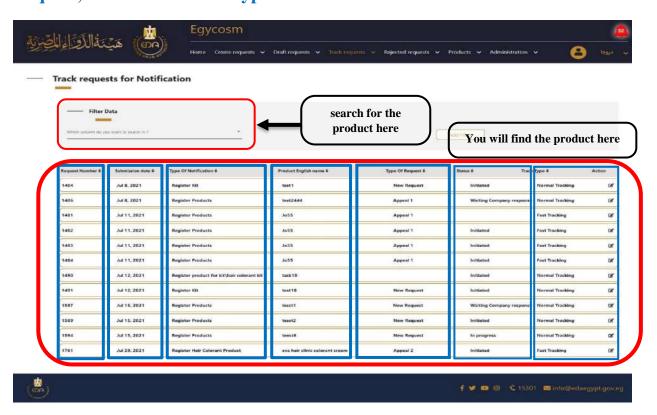
After you have finished entering all the data for the product and press submit then the product will go directly to **Track requests** > **Notification** 



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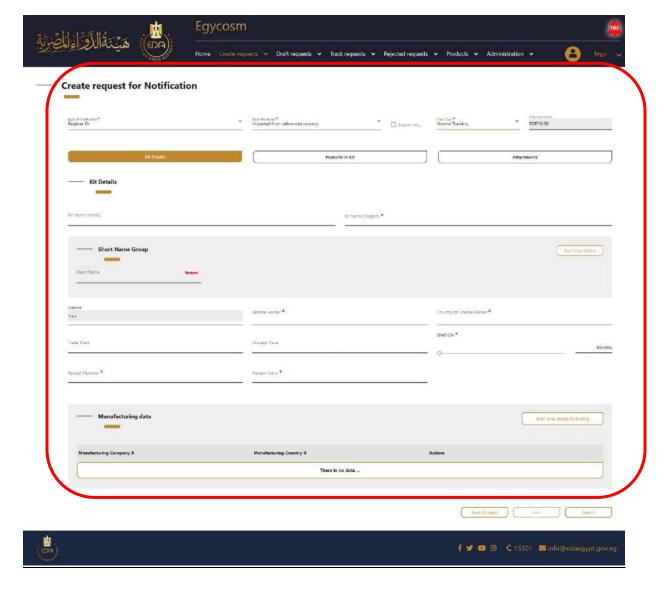
At the Track requests for Notification page there was an attribute table for all the finished requests and submitted successfully classified its Request Number, Submission date, Type Of Notification, Product English name, Type Of Request, Status and Track Type



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# \* In case the type of Notification is Register Kit



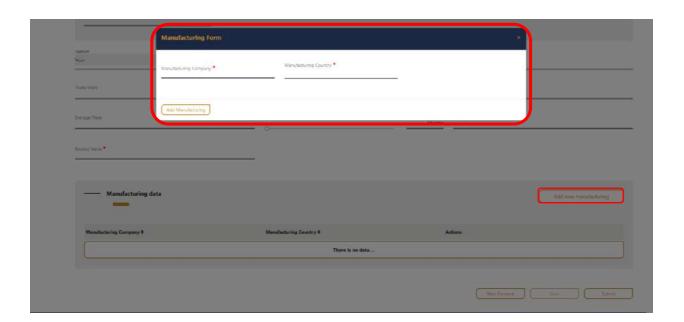
1- After filling at least one field with its custom data the save button will be activated and the request will be saved in draft requests menu > notification tap until you complete all mandatory fields which have small red star on it (\*), in

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Click on add new manufacturing then a pop-up will appears including the form of manufacturing data Consists of:



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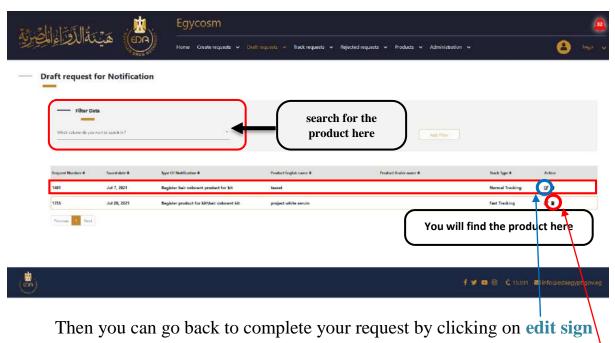
2- You must save the product and it will go directly to **Draft requests**, in order to make sure that the product has been saved and return to complete it again in anticipation of any technical malfunction



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# **Draft requests > Notification page**



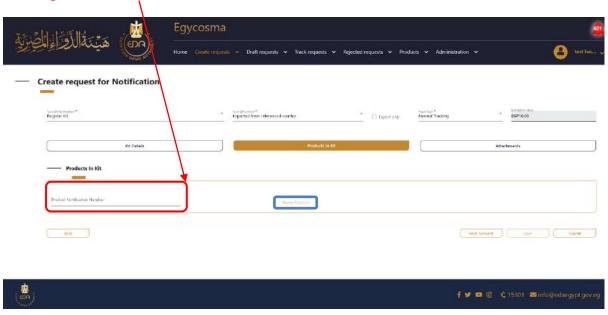
Or remove the request from draft by clicking on **delete sign** 

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❖ The tap of Product in Kit page, choose the product status: approved products

When choose the product from **approved products**, type the notification number of the product here

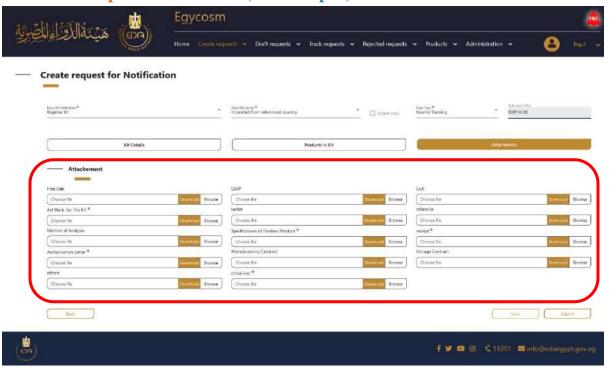


Then click on Apply Product button

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Here you add all the documents related to the product, each in the place designated for it in the tap of attachments (must be pdf)



▲ At the end you make sure that all the mandatory fields are filled with its costume data then click on **Submit button** 

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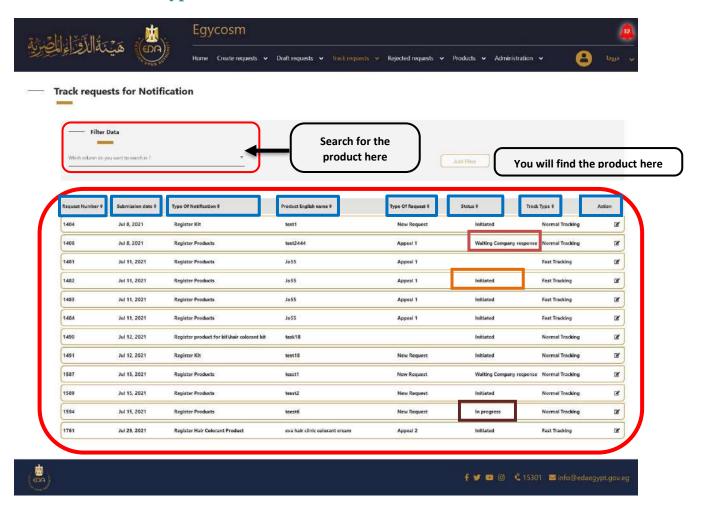
After you have finished entering all the data for the product and press **submit** then the product will go directly to **Track requests** > **Notification** 



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At the Track requests for Notification page there was an attribute table for all the finished request and submitted successfully classified its Request Number, Submission date, Type of Notification, Product English name, Type of Request, Status and Track Type.



1- When you submit, the request status is updated to Initiated

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- 2- In case you get first comment from the authority, the request status is updated to waiting company response and you need to reply to the comments you got and re-submit the request.
- 3- When you re-submit, the request status is updated to **In progress**

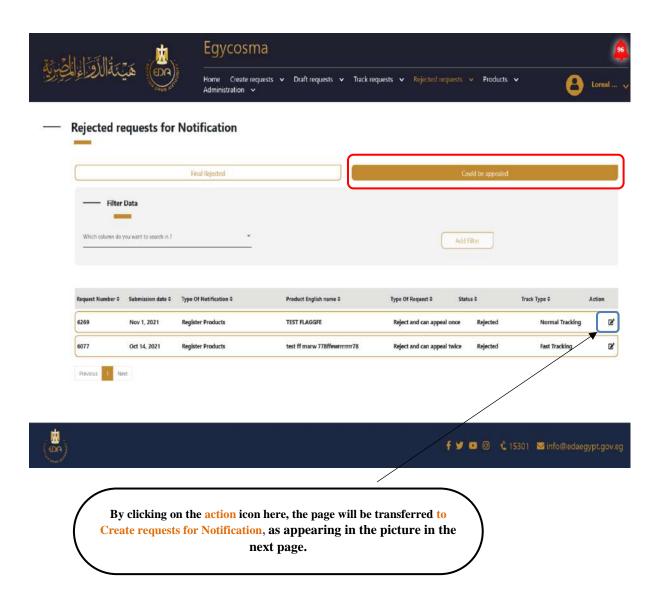
And here in the **Rejected requests for Notification page**, you will get two taps (Final rejected & could be appealed)

- 1. Final Rejected requests are not able to be appealed.
- 2. Could be appealed requests, you can appeal for once or twice as appearing in the Type of request column in the page.



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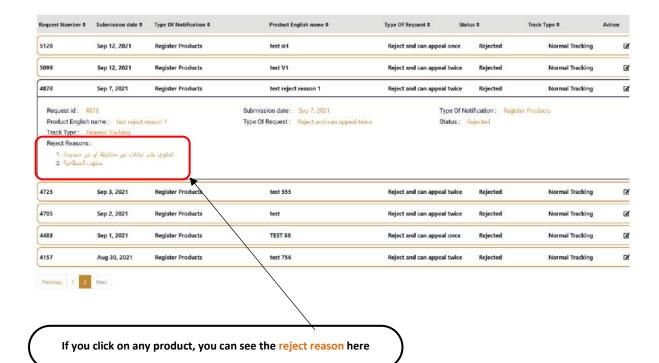


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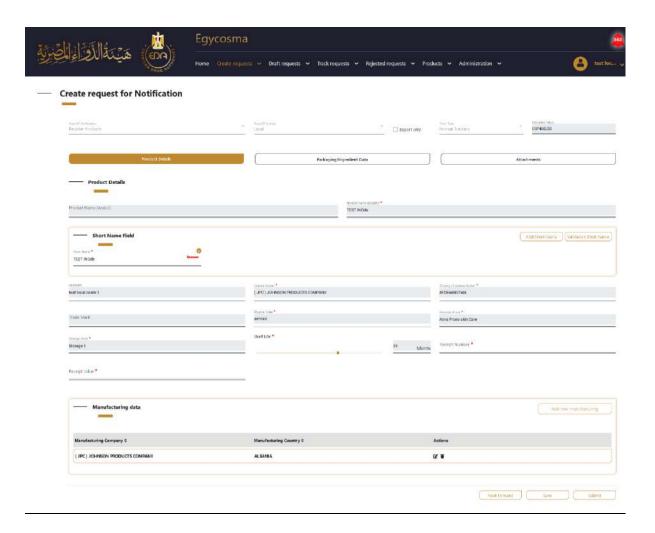


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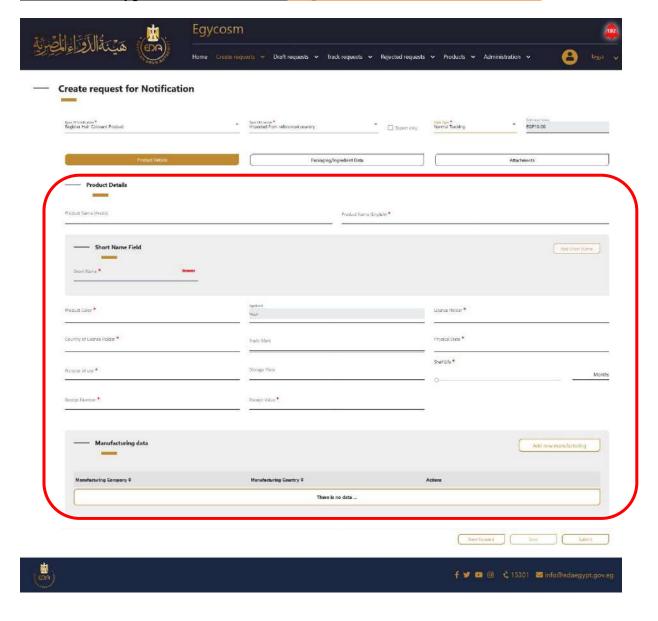




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#### \* In case the type of Notification is Register Hair Colorant Product



❖ After filling at least one field with its custom data the save button will be activated and the request will be saved in draft requests menu > notification

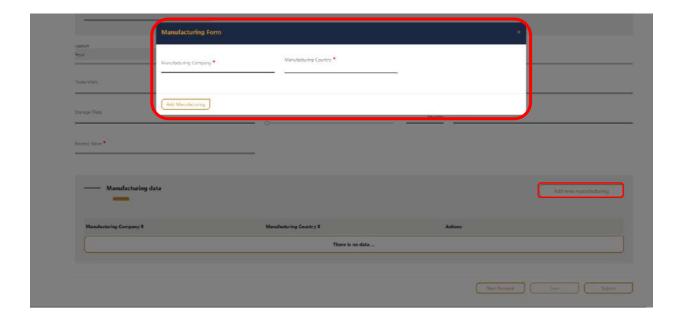
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tap until you complete all mandatory fields which have small red star on it (\*) in the **Type of Notification** page, **Type of license** page and **Track type** page you can able to submit by clicking on **submit** button and the request will transfer to track requests menu > notification tap.

Click on add new manufacturing then a pop-up will appears including the form of manufacturing data Consists of:



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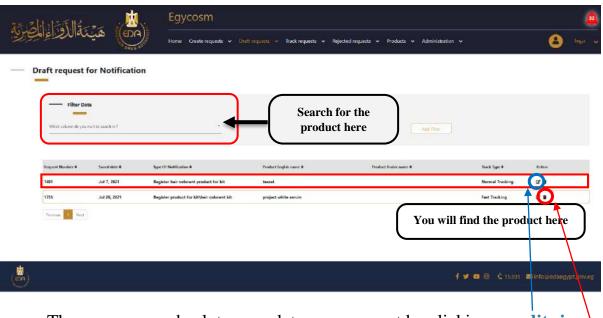
❖ You must save the product and it will go directly to Draft requests, in order to make sure that the product has been saved and return to complete it again in anticipation of any technical malfunction



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## **Draft requests > Notification page**



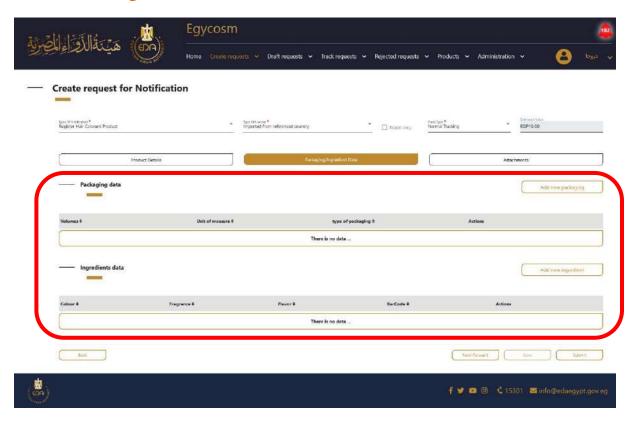
Then you can go back to complete your request by clicking on edit sign

Or remove the request from draft by clicking on delete sign

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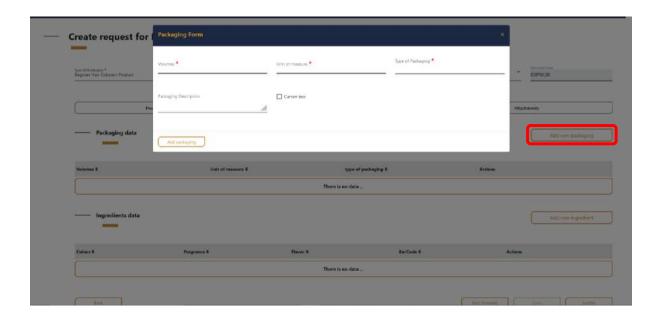
❖ The tap of Packaging/Ingredient Data is divided into two parts packaging data, Ingredient data



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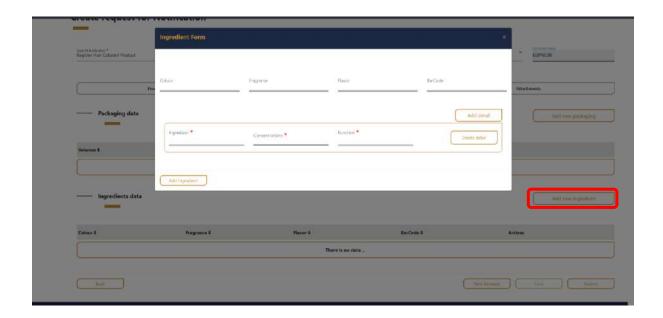
Click on add new packaging then a pop-up will appears including the form of packaging data, Consists of:



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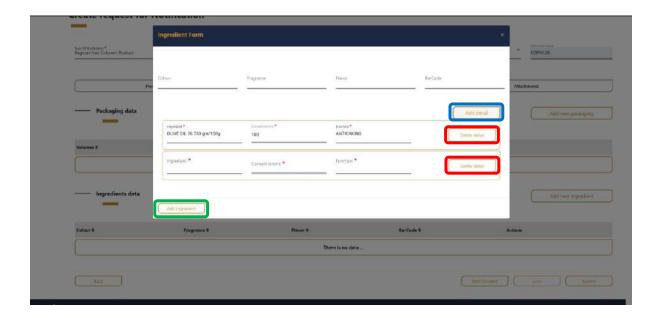
Click on add new Ingredient then a pop-up will appears including the form of details data, Consists of :



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You can add many ingredients or delete them from those buttons and after finishing this step click on add details button

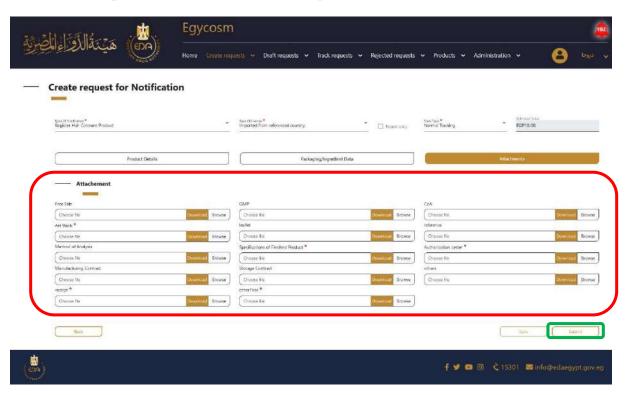


Code: EDREX: NP. CAPP.075





Here you add all the documents related to the product, each in the place designated for it in the tap of attachments (must be pdf)



▲ At the end you make sure that all the mandatory fields are filled with its custom data then click on **Submit** button

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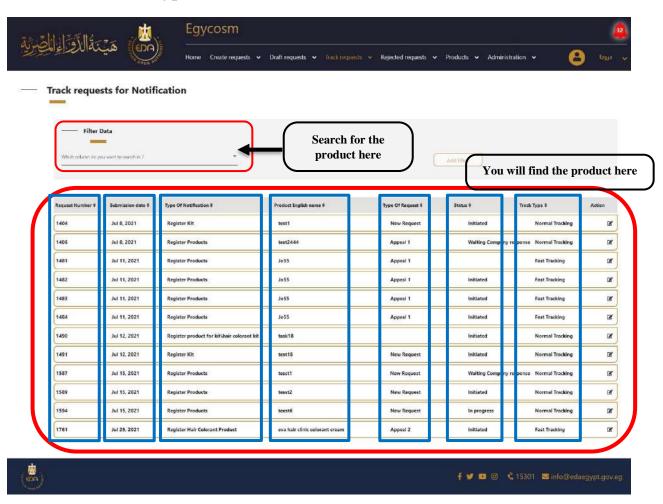
After you have finished entering all the data for the product and press **submit** then the product will go directly to **Track requests** > **Notification** 



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At the Track requests for Notification page there was an attribute table for all the finished request and submitted successfully classified its Request Number, Submission date, Type of Notification, Product English name, Type of Request, Status and Track Type



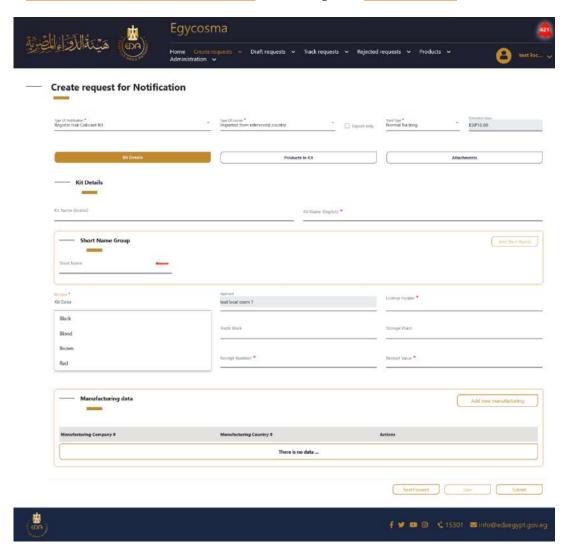
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## \* In case the type of Notification is Register Hair Colorant KIT:

We find that the difference between <u>Register kit and Register Hair Colorant KIT</u> in the field of color kit and <u>Register Hair Colorant KIT</u> can apply register product and register hair colorant product

\* Register Hair Colorant KIT Same steps of Register kit

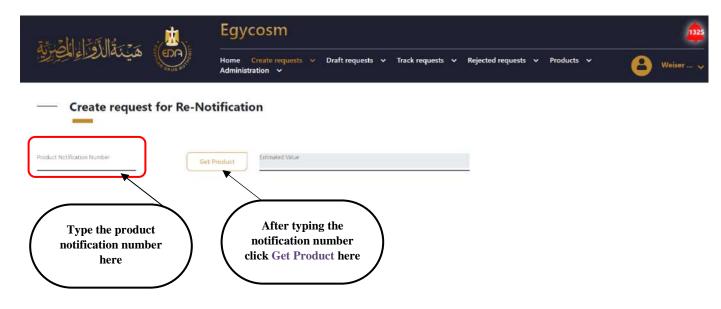


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## **\*** Create requests for Re-Notification,

This page is created for Products which reached or passed 9/10 years on the system.

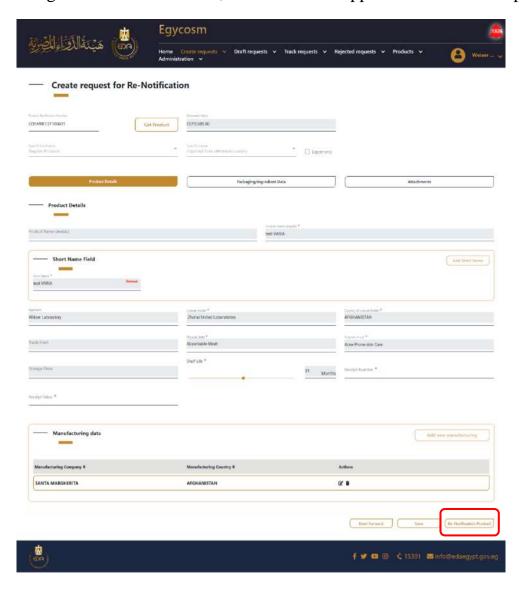




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After clicking on Get Product icon, the screen will appear as in the below picture.

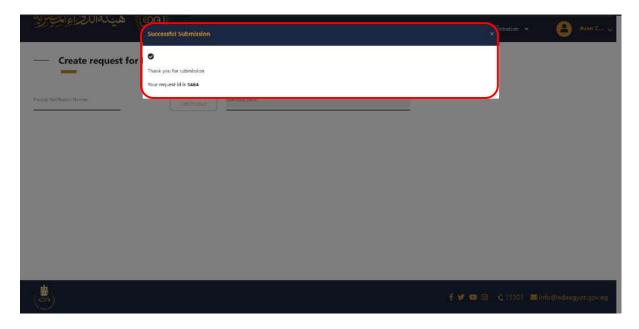


This page containing the Product details, first you should fill the fields and attachments that marked with (\*) and at the down right side of the page you will find **Re-Notification Product** icon, click on it.

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After clicking on **Re-Notification Product**, you will get a pop-up message as in the picture below.

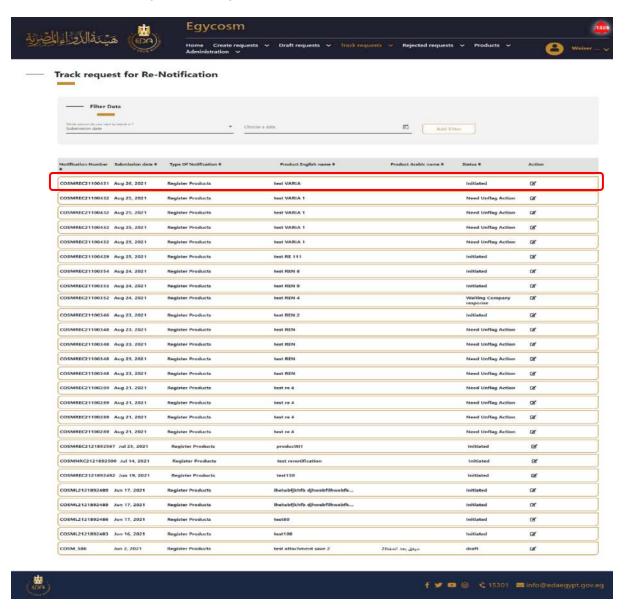


Take a copy of the request notification number which in the pop-up message to follow the status of your request in the **Track request for Re-Notification** page.

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And here is your request appears at the top of the list as in the picture below.

Ps: the list already sorted by default from newest to oldest.

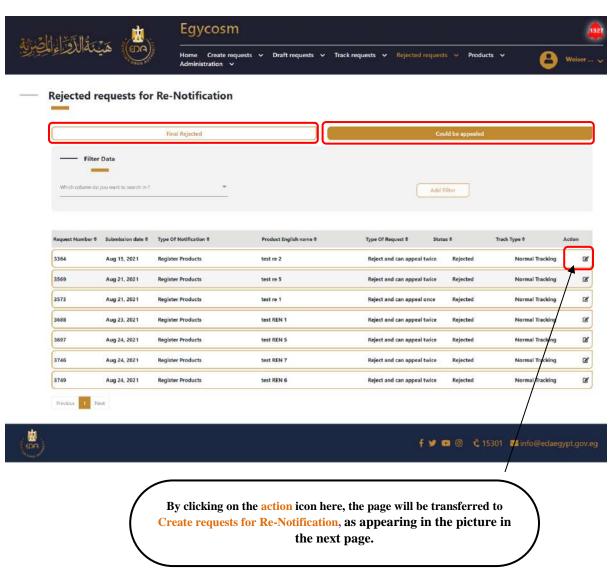


Code: EDREX: NP. CAPP.075



And here in the **Rejected requests for Re-Notification** page, you will get two taps (Final rejected & could be appealed)

- Final Rejected requests are not able to be appealed.
- Could be appealed requests, you can appeal for once or twice as appearing in the Type of request column in the page.

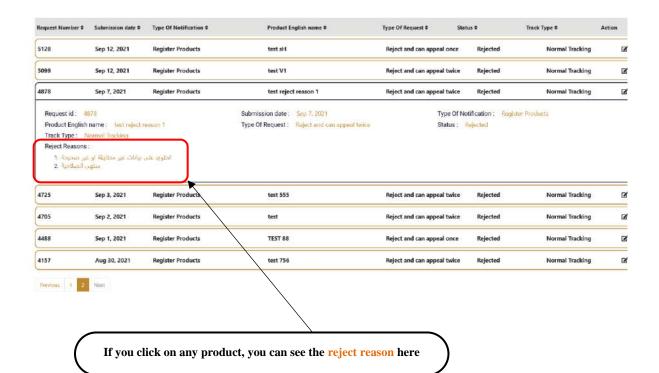


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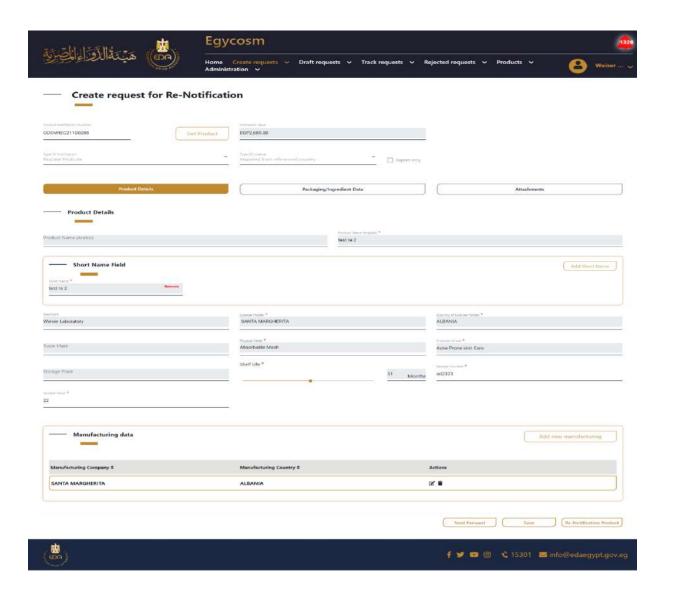


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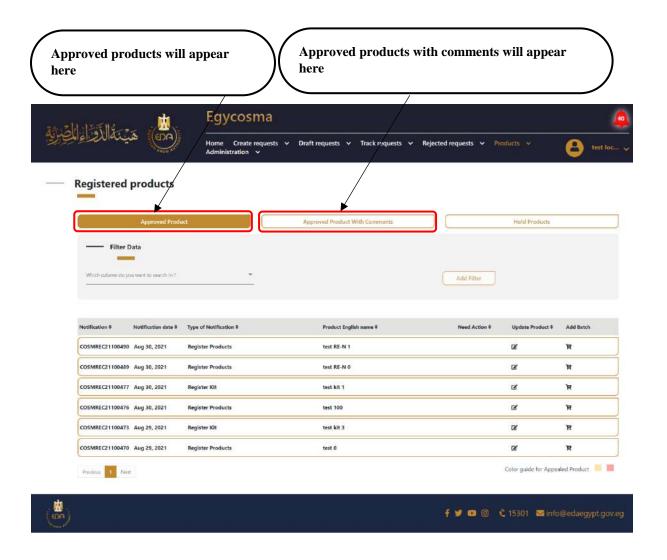
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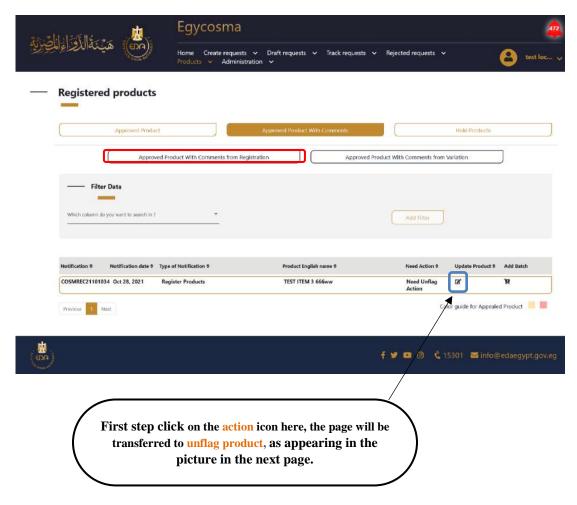






Approved products with comments from registration (FLAG) as in the below picture, and these products need (UNFLAG) action

- ❖ In this process You don't have to pay extra fees to unflag the product
- ❖ You only need to fulfill the request by responding to the comments coming from the authority



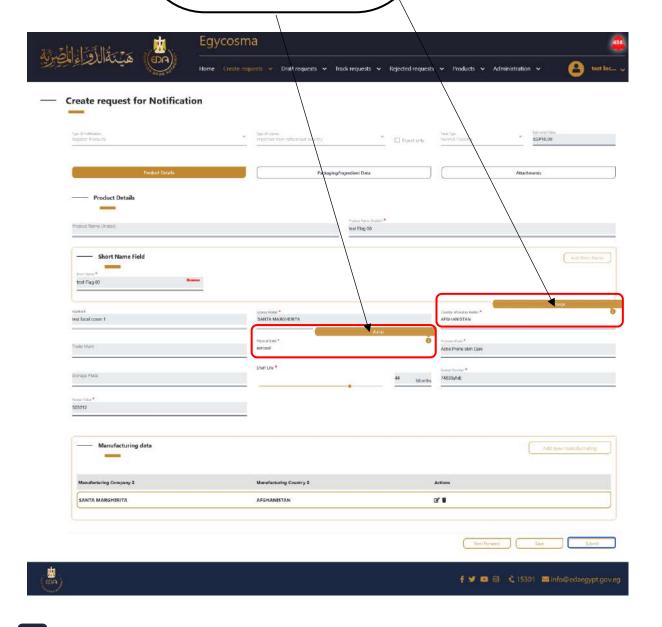
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In this step you need to check all comments you have and click submit after you reply to the required changes



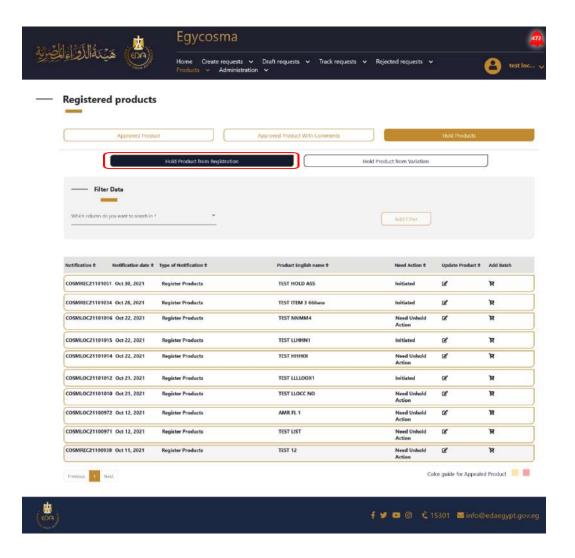
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Hold products from registration as in the below picture, and these products need (UNHOLD) action.

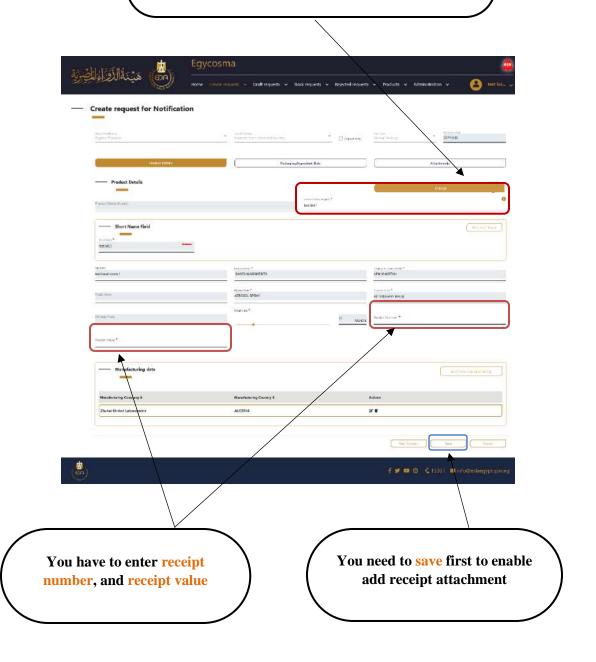
- ❖ In this process, you will have to pay extra fees to unhold the product
- ❖ You need to fulfill the request by responding to the comments coming from the authority



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In this step you need to check all comments



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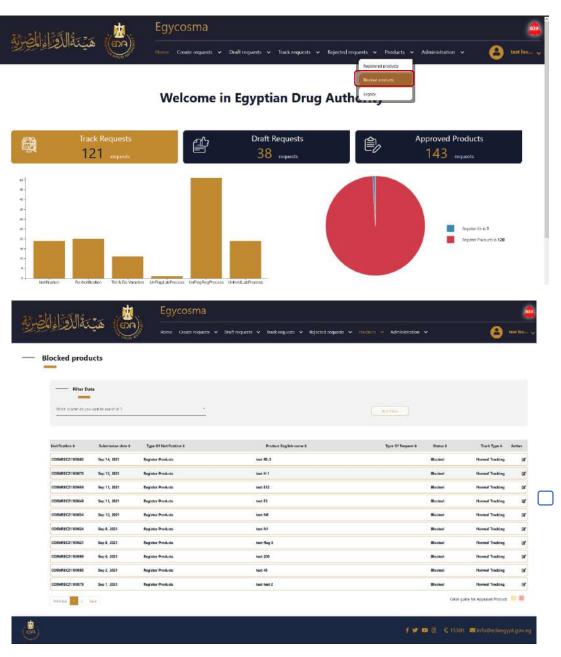
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You need to add receipt attachment once you complete this step you can click submit Egycosma هَيْنَةُ الدَّوِّ إِذِ الْحِيْرَةِ Home Create requests ♥ Draft requests ♥ Track requests ♥ Rejected requests ♥ Products ♥ Administration ♥ Create request for Notification EGP10.00 □ foot only Product Details ng/ingresilent Data Free Sale Chance file throwse Choose No fronse Art Work\* Browse Method of Analysis Authorization letter.pdf III Bronne Browse Choose file Choose Ne Choose the Browse Shat the Browse Choose tile letter of variation from license holder Choose file Downsood Browse Browse Registration Liberse 5ex ∮ 🥩 🔞 🎯 🐧 15301 🖼 info@edaegypt.gov.eg

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**Blocked products** in the below picture, once product reject from unhold process the product appear direct in **blocked product** and **You cannot take any action**.



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Product read only in blocked product You cannot take any action

Type O' Hellington Regulator Products	Tair O'Clarier Insport and Country Insport in Country Insport in Country Insport Inc.	□ Export only	Neth Total Planniel Triacking	EGP10.00
Product Details	Packaging	yIngredient Cuta		Attachments
Product Details		Product Starral Straphets *		
Product Name (Arabic)		teet RE 3		
Short Name Field				Add Start Name
Strait Sales A				
test RE3				
Applicant	Suppliedate *		Covery If Lorest House *	
test focal comm 1	SANTA MARGHERITA		AFCHANISTAN	
	Pytokiala *		Purpose of last *	
Trada: Maris	aerosoli		AFTERSHAVE BALM	
Storings Hizzw	Shalf Life *		Salaya Number *	
STOCK MILE PROCESS		26 Months	56435yhdj	
53252				
225,45				
Manufacturing data				Add new manufacturing
_				
Manufacturing Company \$	Manufacturing Country #		Actions	
	ourous ex		2 <b>8</b>	
SANTA MARGHERITA	ALBANIA			

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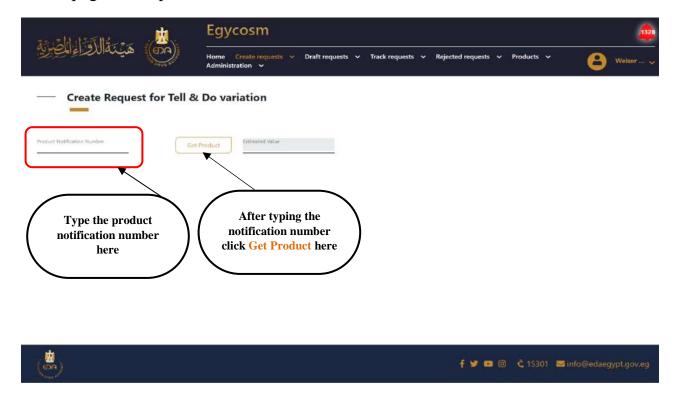
Code: EDREX: NP. CAPP.075



## **\*** Create request for Tell & Do Variation,

And here if you want to make some changes on a product:

-Select Tell & Do Variation from Create requests list and it will take you to the below page in the picture.



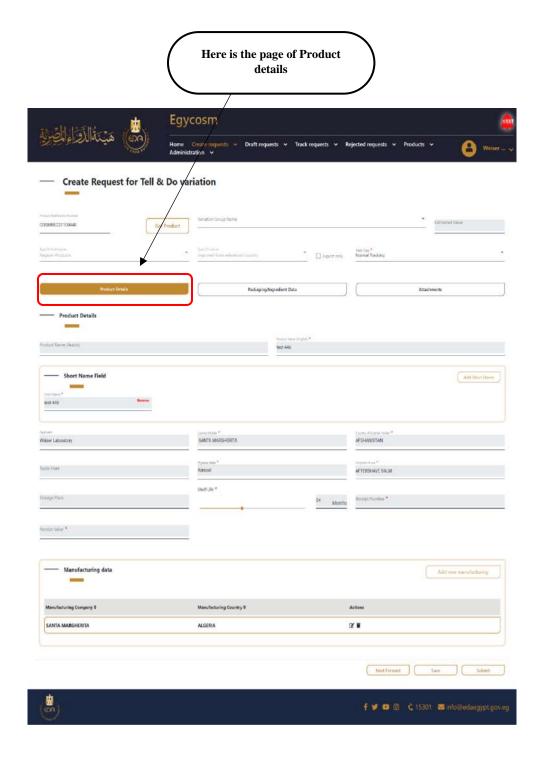
After typing the product notification number, and click Get product, the screen will be as is in the picture in the next page.

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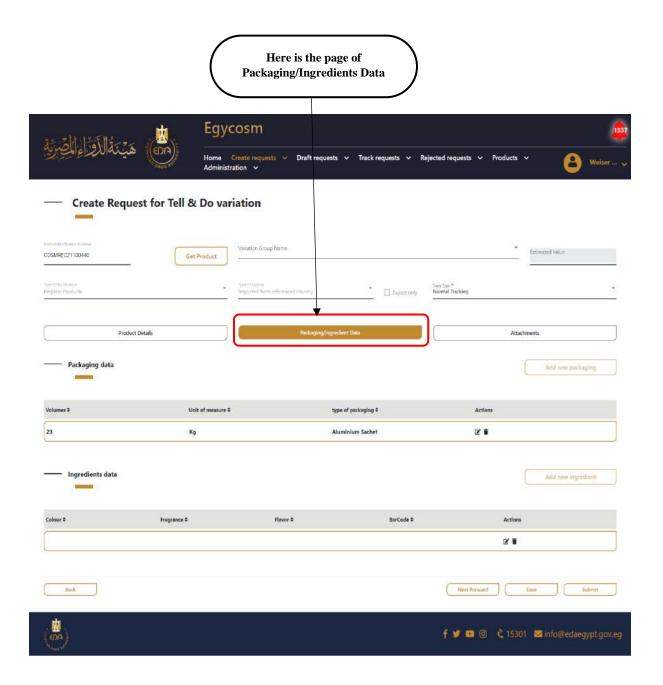
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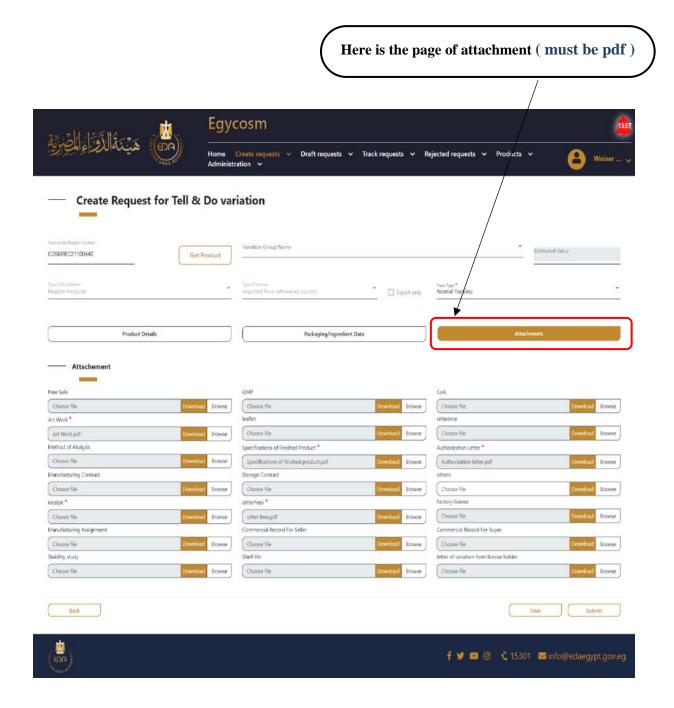










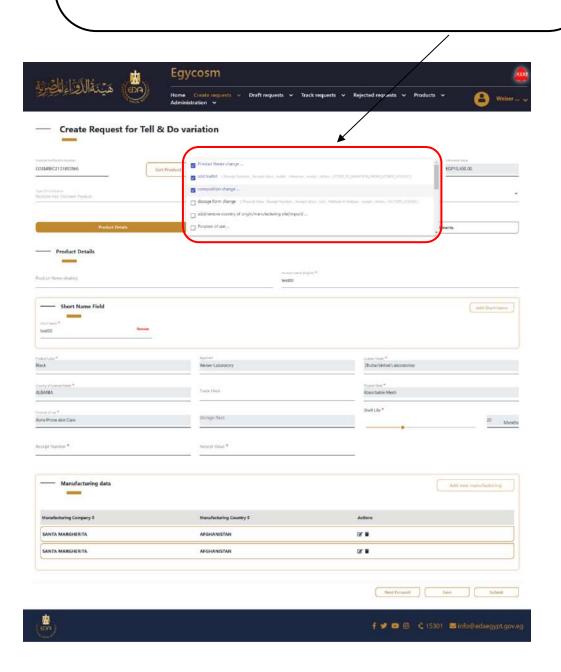




				Choose the here (normal fast tra	tracking or
	Egycosm				á
هيئه الأفراء المصرية	Home Create requests Administration	<ul> <li>Draft requests</li> <li>Track requests</li> </ul>	<ul> <li>Rejected requests</li> </ul>	∨ Products ∨	(a) Weiser
Create Request for	r Tell & Do variation				
Product hamfornias Romani COSMREC21100440	Get Product	nie		* Estimate	ed Value
ius DYNesfatos Beginter Prodúctis	Town DY Lowest imported from refer	noced country Dipo	here type * Normal Tracking	V	-
Product Details		Packaging/Ingredient Data		Attachments	
Product Details					



Here is we choose from the list of variation group name, (Product name change & add leaflet & composition change)



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- ❖ If company need to choose a type of variation ( ownership transfer )
- Please go to the admin of variation in the authority and follow the procedures for that process .

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when you choose group of variation you need to click

Notice to applicant

Choose the variation group name from the list here, and please note that the fields which will be appeared in the page are depends on your choices from the list.

apply variation group to open fields of this groups Egycosma Create Request for Tell & Do variation COSMREC21101178 Set Product - Short Name Field ( JPC ) JOHNSON PRODUCTS COMPANY AEROSOL SPRAY AFTERSHAVE BALM 52 Months Manufacturing data Manufacturing Country = ( JPC ) JOHNSON PRODUCTS COMPANY 2 T Next Forward Save Submit

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Here are the appeared fields for what we choose from the list in variation group name Egycosm Create Request for Tell & Do variation COSMREC21100440 test 446 5,000.00 ALGERIA f 🎔 🚥 🎯 🐧 15301 🐱 info@edaegypt.gov.eg

You must fill all the fields which have (\*) mark.

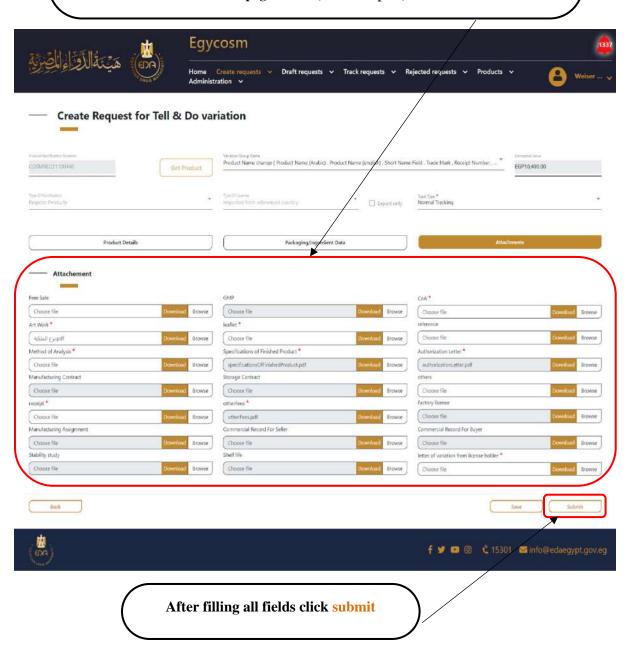
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And also attach the files for fields which have (\*) in the attachment page as shown in the page below. ( must be pdf )

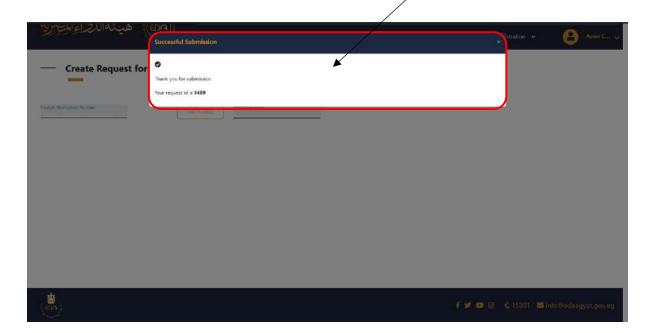


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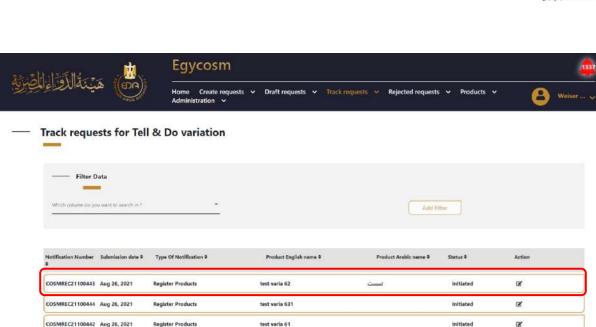
After clicking submit, a pop-up message will appear confirmed that your submission is successfully done, as appearing in the below picture.



Then we will go to Tell & Do Variation in the Track requests list, and we will find the product appears as is in the below picture.

Ps: the list already sorted by default from newest to oldest.

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test varia 60

test varia 60

test 205

test 2061

test 7771

test product variation 3

After that, you will see the response in the status column as in the below picture.

COSMREC21100441 Aug 26, 2021

COSMREC21100441 Aug 26, 2021

COSMREC21100409 Aug 26, 2021

COSMREC21100410 Aug 26, 2021

COSMREC21100439 Aug 26, 2021

COSMREC21100404 Aug 25, 2021

Register Products

Register Products

**Register Products** 

Initiated

Initiated

Initiated

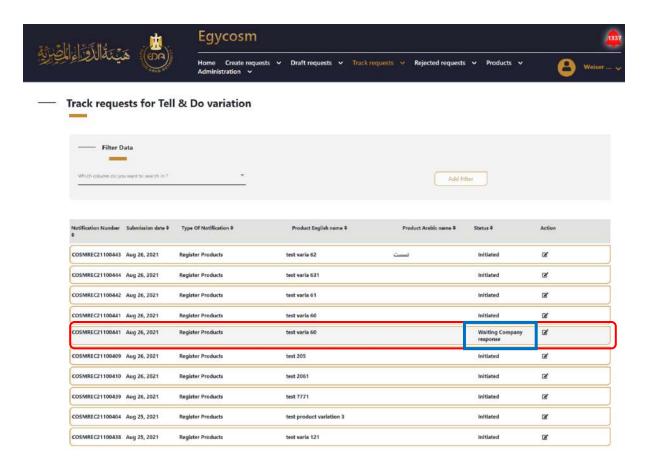
Initiated

B,

B,

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Then after the EDA revision user approve, the product will be moved to the Register **Products** list as in the picture in the next page.

Ps: It might be final approve, or reject if the revision user added some comments on your request. There are two times the authority allows them to wait for the company's response to the required comments, and the third time, the request will be rejected

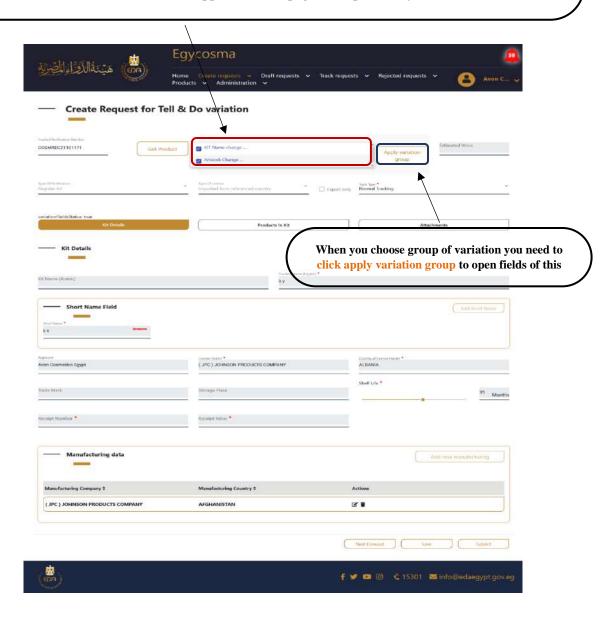
Code: EDREX: NP. CAPP.075



### **Create request for Tell & Do Variation for (KIT)**

And here if you want to make some changes on a KIT:

Choose the variation group name (KIT Name change, ARTWORK Change) from the list here, and please note that the fields which will be appeared in the page are depends on your choices from the list.



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Create request for Do & Tell Variation,

-Select Do & Tell Variation from Create requests list and it will take you to the below page in the picture.

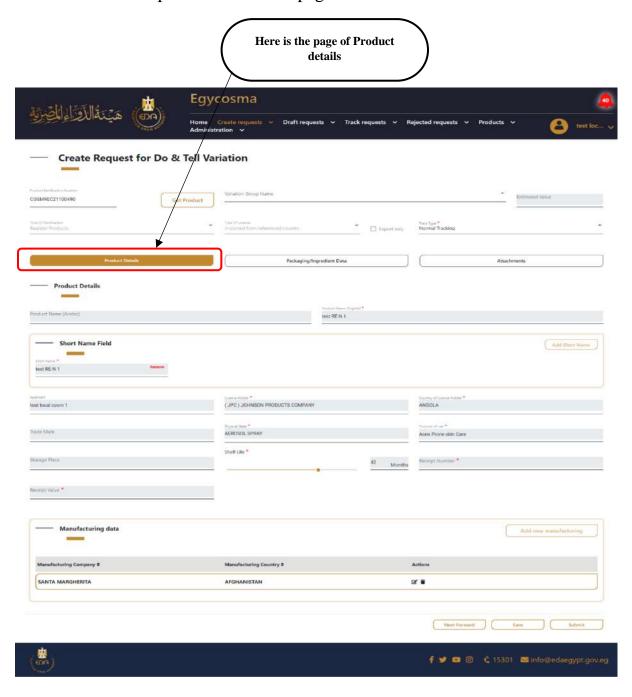




Code: EDREX: NP. CAPP.075



After typing the product notification number, and click **Get product**, the screen will be as is in the picture in the next page.

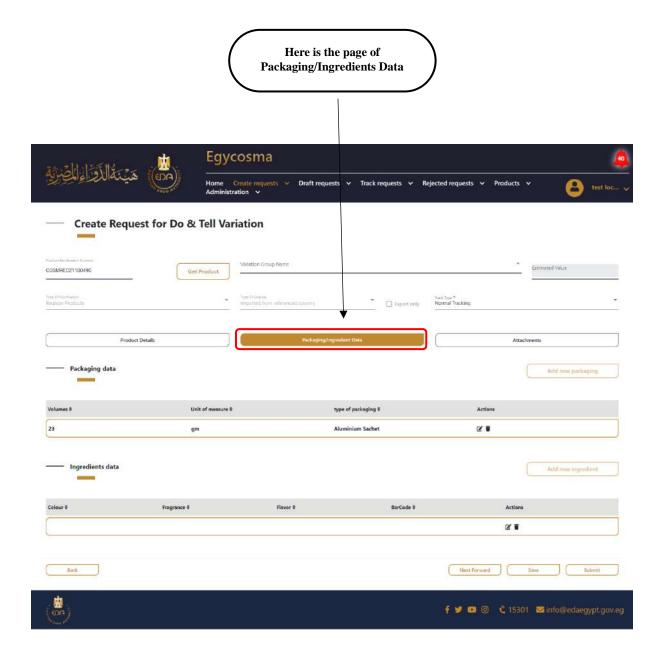


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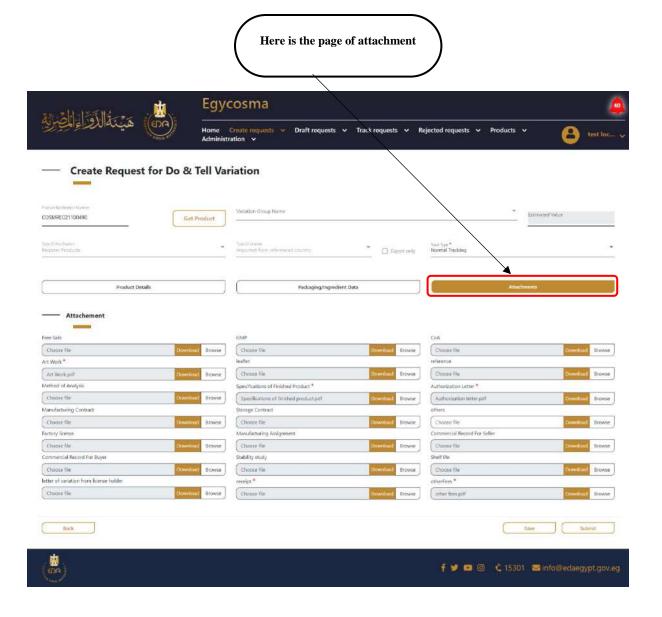
Code: EDREX: NP. CAPP.075





Code: EDREX: NP. CAPP.075

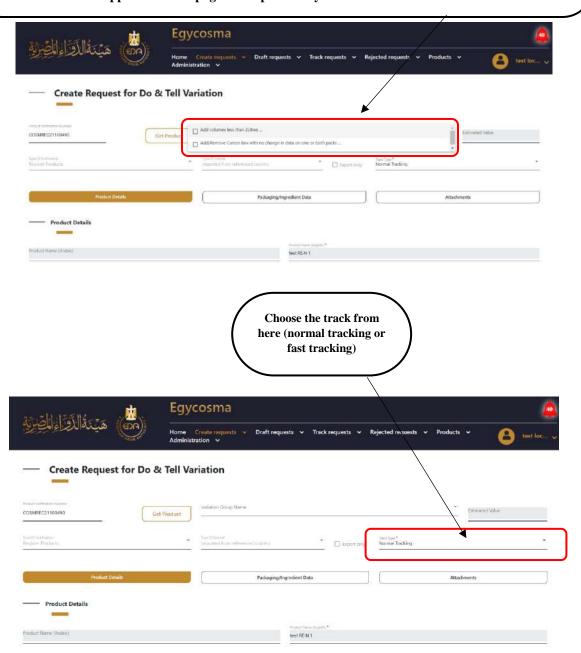




Code: EDREX: NP. CAPP.075



Choose the variation group name from the list here, and please note that the fields which will be appeared in the page are depends on your choices from the list.



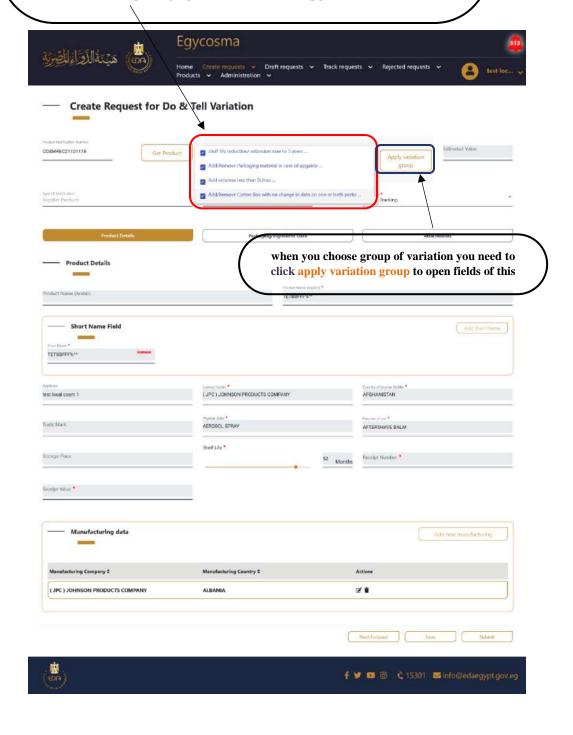
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Here we have only two options of variation group name, (add volumes less than 5 liters & add/remove carton box with no change in data on one both packs & shelf life reduction/ extension max 5 years & Add/remove packaging material in case of upgrade)



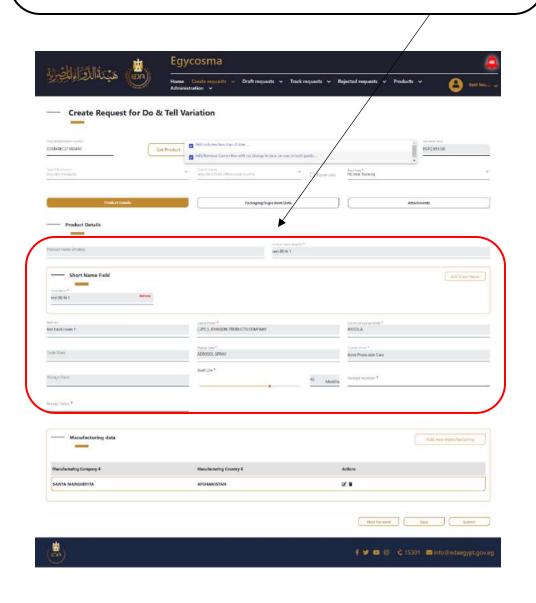
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Here are the appeared fields for what we choose from the list in variation group name

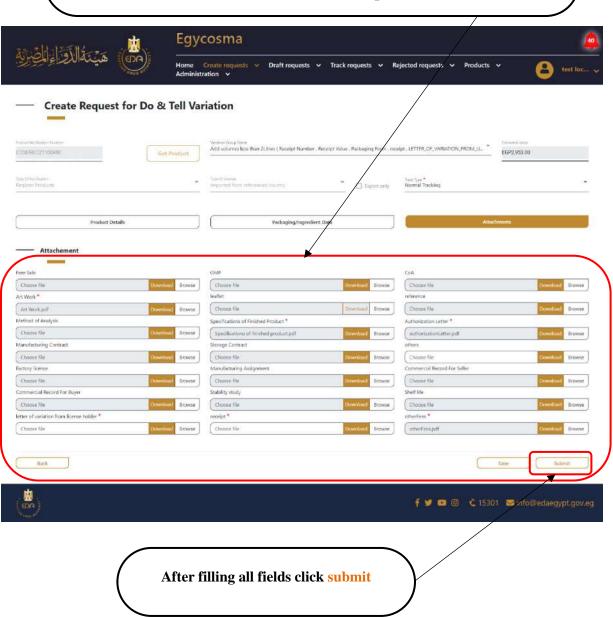


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You must fill all the fields which have (\*) mark.

And also attach the files for fields which have (\*) in the attachment page as shown in the page below. ( must be pdf )



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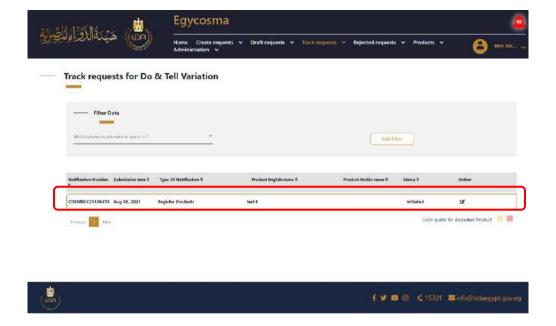
After clicking submit, a pop-up message will appear confirmed that your submission is successfully done, as appearing in the below picture.



Then we will go to Do & Tell Variation in the Track requests list, and we will find the product appears as is in the below picture.

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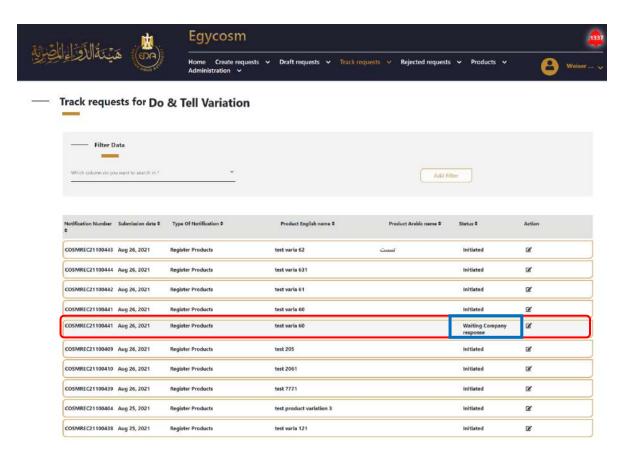




After the EDA revision user approve, the product will be moved to the Register Products list as in the picture below.

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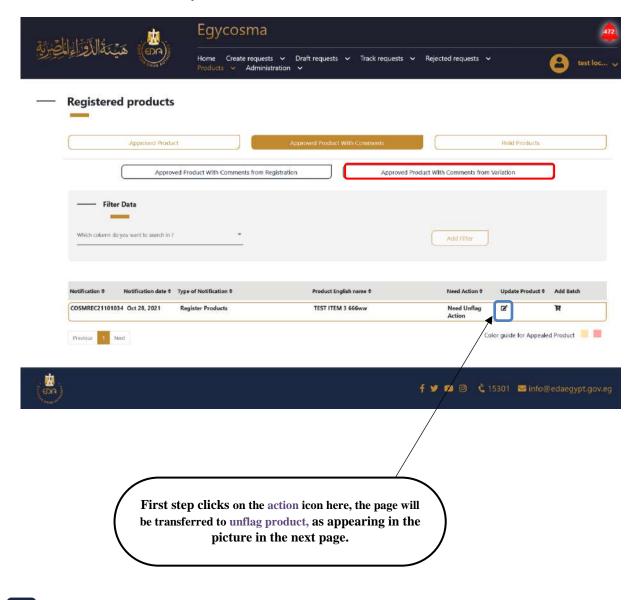
Ps: it might be final approve, or reject if the revision user added some comments on your request. There are two times the authority allows them to wait for the company's response to the required comments, and the third time, the request will be rejected

Code: EDREX: NP. CAPP.075



Approved products with comments variation (FLAG) as in the below picture. and these products need (UNFLAG) action

- ❖ In this process You don't have to pay extra fees to unflag the product
- ❖ You only need to fulfill the request by responding to the comments coming from the authority



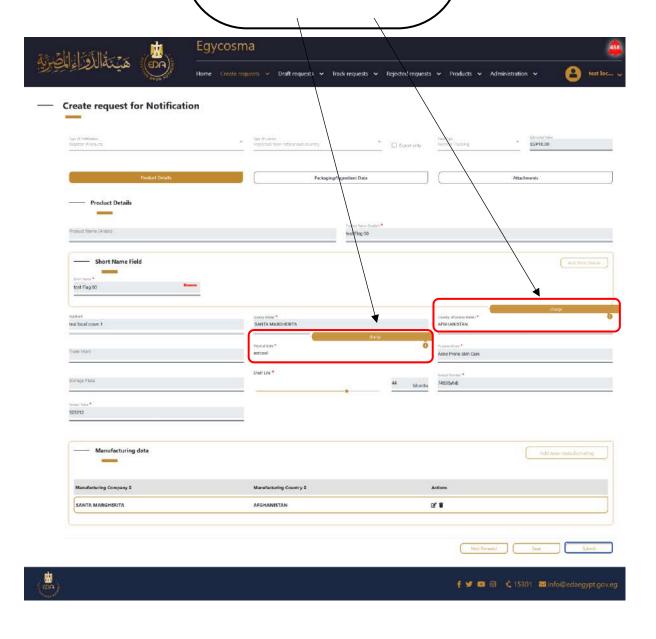
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In this step you need to check all comments you have and click submit after you reply to the required changes



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Hold products from variation as in the below picture. and these products need **(UNHOLD)** action.

- ❖ In this process, you will have to pay extra fees to unhold the product
- ❖ You need to fulfill the request by responding to the comments coming from the authority

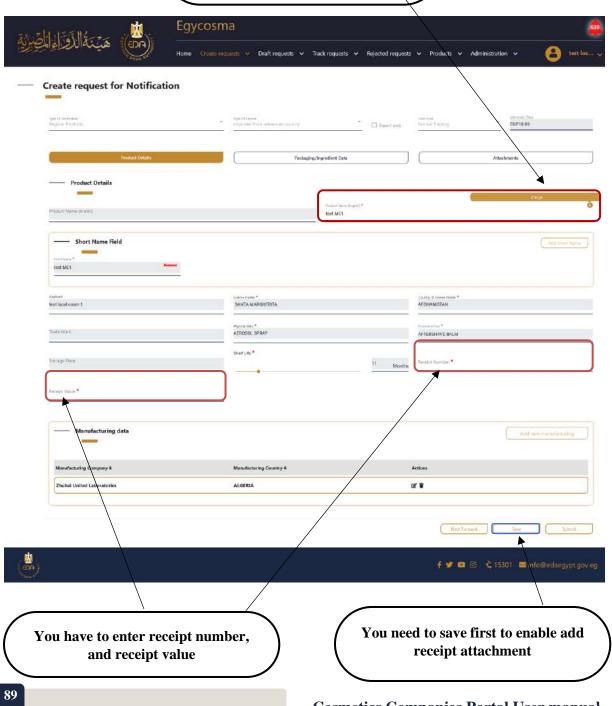




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# In this step you need to check all comments

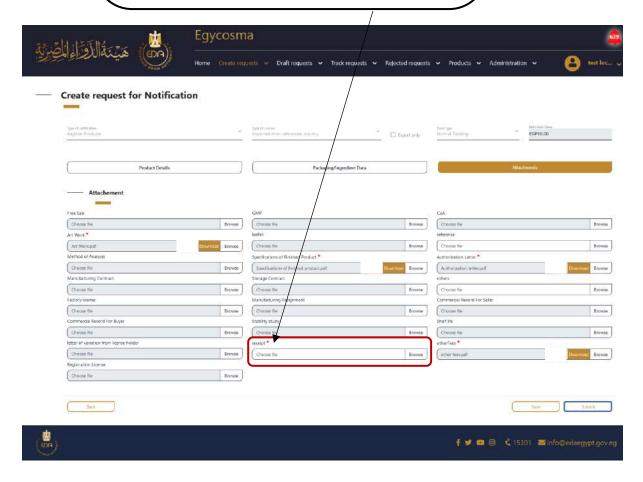


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You need to add receipt attachment once you complete this step you can click submit



The last step for request rejection Hold of variation

- Company in this step (do unhold request)
- When Authority rejects (the request return in this step) and do unhold request again (forever)

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## **4-General Enquiries**

And here if you have any enquiry from the EDA, go to Create request list, then click on General Enquiries, and the screen will appear as in the picture below.





All of the fields are mandatory, after filling it all click **submit**, then go to **Track** request list, then click on **General Enquiries**, and you will find your enquiry as in the picture in the next page.

Code: EDREX: NP. CAPP.075







## 5- Legacy

And here you will find all of products that have been recorded and approved before on the system, so you can update any product you want.

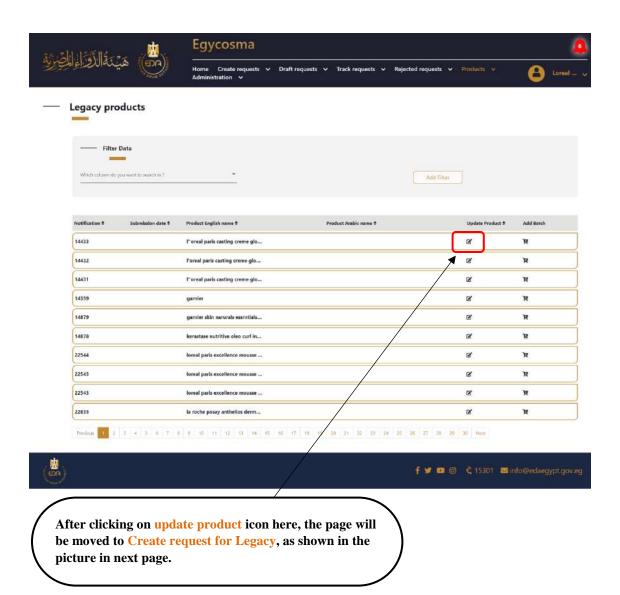
-Go to Products tap, then click on Legacy, and the screen will appear as in the picture below.

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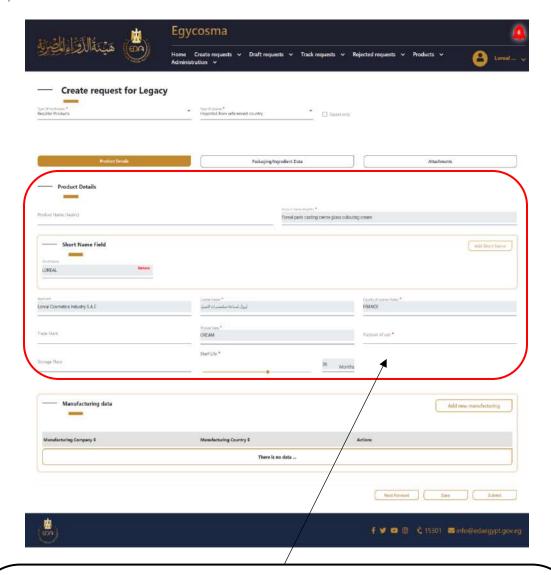
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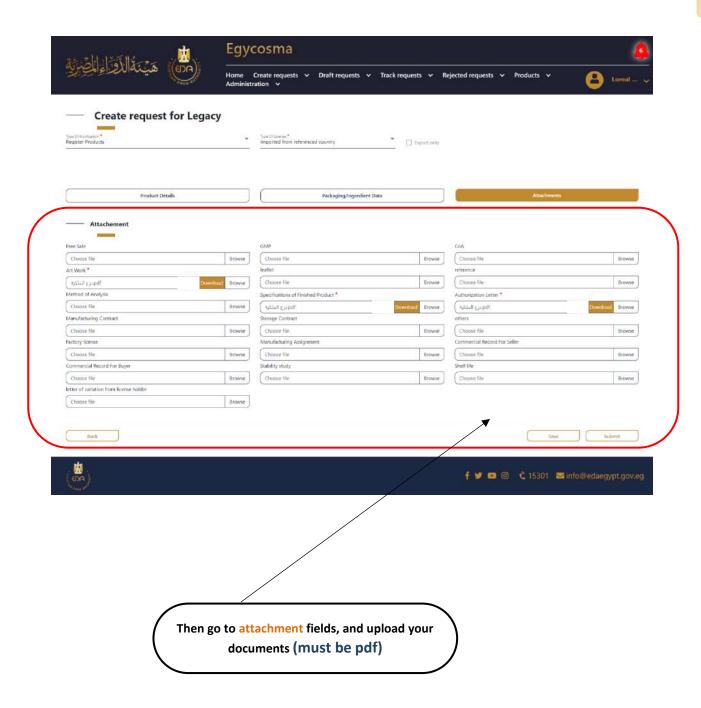
Here is the same process as creating request for notification, so you can fill the fields, and after that click on Submit.



Here are the available fields that you can update, but the basic fields which have been filled before can't be edited like (type of notification/ type of license/ product name "English"/ short name field/ applicant/ license holder/ country of license holder/ physical state/ shelf life)

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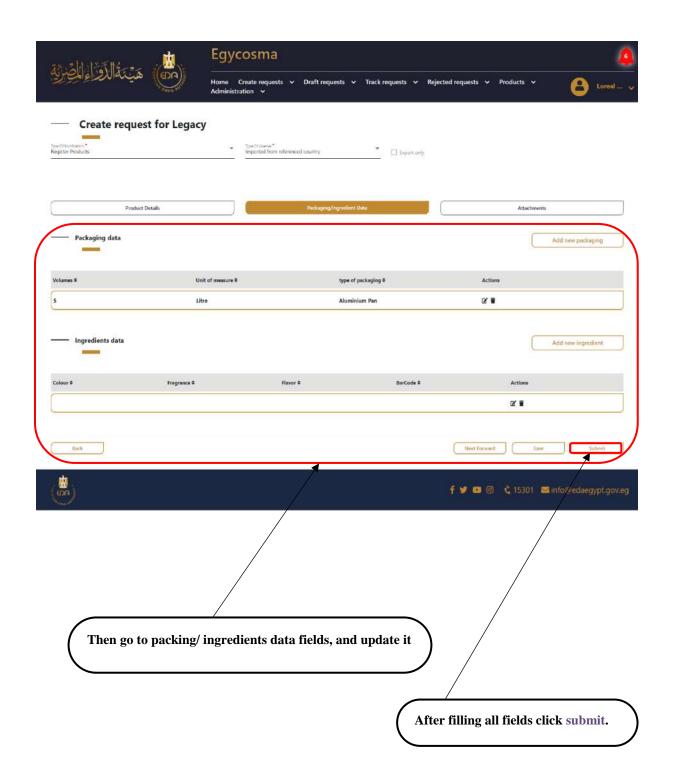


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After clicking submit, the page will be moved to Track request for Legacy, and you will find your product in the list as shown in the picture below.





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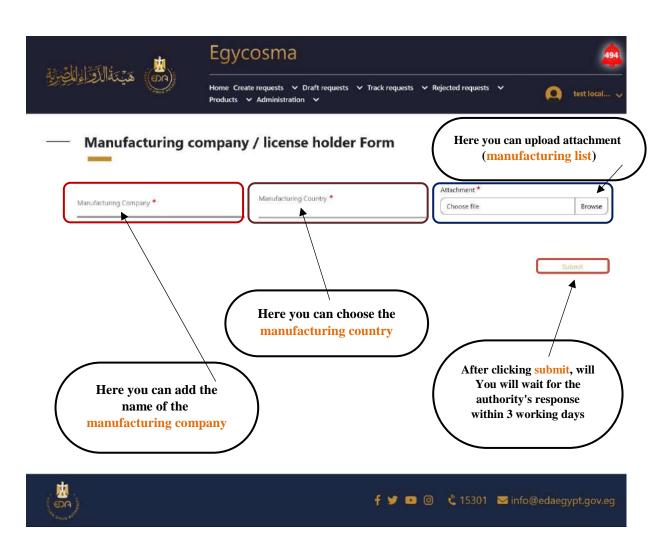


## **6- Add Manufacturing company / license holder**

In the case of adding manufacturing company, you can add from this list.



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#### **General Notes**

- ❖ يجب التأكد من عمل أي متغير على المستحضر قبل التقدم لإعادة الإدراج فلا يمكن إجراء أي متغير خلال الإعادة وفي حال وجود متغير أثناء الإعادة يتم رفض الطلب والتقدم لقسم المتغيرات وإعادة تقديم طلب الإعادة برسوم جديدة.
- ♦ يجب أن يكون ال short name جزء من long name ويجب التأكد من كتابته في الجزء الخاص ب short name في البرنامج.
- ❖ في حالة التنازل ونقل ملكية المستحضرات لشركة أخرى لا يجوز لكل من الشركتين عمل line
   ❖ brand كله .
- ❖ في حالة إدراج ال kit يتم إدراج كل مستحضر على حدة ثم التقدم بطلب إدراج الkit في حال رغبة الشركة
- ❖ يجب التأكد من نوع التسجيل ونوع المستحضر ونوع الطلب وفي حالة خطأ الشركة في تقديم نوع التسجيل (مستورد مرجعي، غير مرجعي، محلي، أو مصنع لدى الغير) أو نوع المستحضر (مستحضر عادي أو صبغه او kit ) أونوع الطلب (fast or normal) يتم رفض الطلب وإعادة تقديمه برسسوم جديد.
- ❖ لا يتم تقديم التماس لتعديل بيان التركيب للمستحضرات المستوردة وفي حالة تقديم الالتماس يتم رفضه.

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- ❖ يجب التأكد من وجود خط إنتاج موضح في رخصة المصنع قبل التقدم للإدراج وفي حالة عدم وجود خط انتاج تلتزم الشركة بتغيير مكان التصنيع .
- ♦ في حال رفض طلب الإدراج للشركة الحق في تقديم التماسين للطلب الواحد ثم يتم بعدها إسقاط الطلب وتقديمه من جديد برسوم جديدة.
  - ❖ لا يتم إجراء أكثر من عملية على المستحضر في نفس الوقت.
- ♦ في حاله مستحضر (approve with comment(flag) لا يتم إجراء أي عملية عليه إلا بعد استيفاء .comment (unflag)
- ❖ يجب تقديم طلب اعاده ادراج المنتج قبل ٣ شهور من انتهاء صلاحيه الادراج حتى تتمكن الشركة من تقديم ٢ التماس للمستحضر في حالة الحاجة لأنه في حالة انتهاء مدة الإعادة لا يتم عمل أي إجراء على المستحضر.
- ♦ أي التماس مقدم من الشركة إلى الهيئة أثناء الإدراج المدة الزمنية المحددة له ٣٠ يوم بعدها يتم إسقاط الطلب و لا يمكن استكماله ويقدم كمستحضر جديد.
  - في حاله الاحتكام إلى مرجعيه التداول تكون شهادة التداول إجبارية وموثقة من السفارة المصرية.
  - ❖ وفى حال الاحتكام إلى مرجعية التصنيع تكون قائمة المصانع إجبارية وموثقة من الغرفة التجارية.

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- ♦ في حاله تسجيل مستحضرات الصبغة أو hair colorant kit يجب إضافة اسم الجروب مع اسم المستحضر في long & short name.
- ❖ في حالة reject of variation مدة استيفاء ال comments هي ١٠ يوم في حالة الرفض الأولي و ١٥ يوم في حالة الرفض الثانية و لا يمكن للشركة في حالة الرفض الثالث التقدم بالتماس بل يجب تقديم الطلب مرة اخرى برسوم جديدة .
- ❖ في حالة إدراج مستحضر متعدد الألوان، الروائح، النكهات، أو جميعهم يتّم إضافة مقابل الخدمة التابع
   لكل فئة إلى رسوم الإدراج الموضحة في ال Estimated value وفقا لقائمة مقابل الخدمات المقررة.
- ❖ تتم مراجعه طلب الإدراج وارسال comment للشركة بدون مقابل مادي لمرة واحدة فقط لما يخص استيفاء الطلب لمتطلبات الإدراج وفقا للدليل التنظيمي (check list) ويستوجب على الشركة الاستكمال خلال 15 يوم ثم تتم المراجعة الفنية للطلب وإصدار القرار النهائي إما بالموافقة وصدور رقم الإدراج أو الرفض وفي هذه الحالة من حق الشركة الالتماس مرتين للطلب الواحد
  - ❖ يجب دفع مقابل الخدمات وتسليم أصل ايصال الدفع للإداري المختص قبل ارسال طلب الإدراج
- ب يجب على الشركة احضار الأصول الموثقة للصيادلة العاملين بالادارة للاطلاع على الاصول قبل رفعها على البرنامج

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