هيئة الدواء المصرية

Egyptian Drug Authority

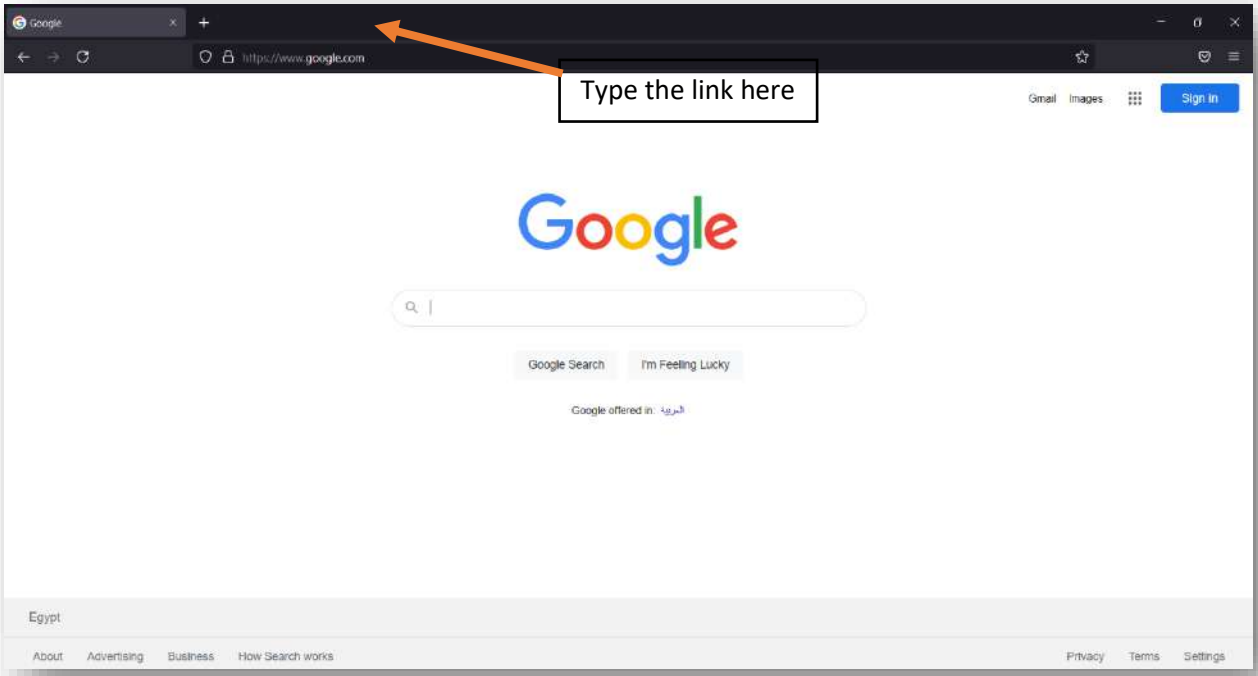
Cosmetics Companies Portal

User manual

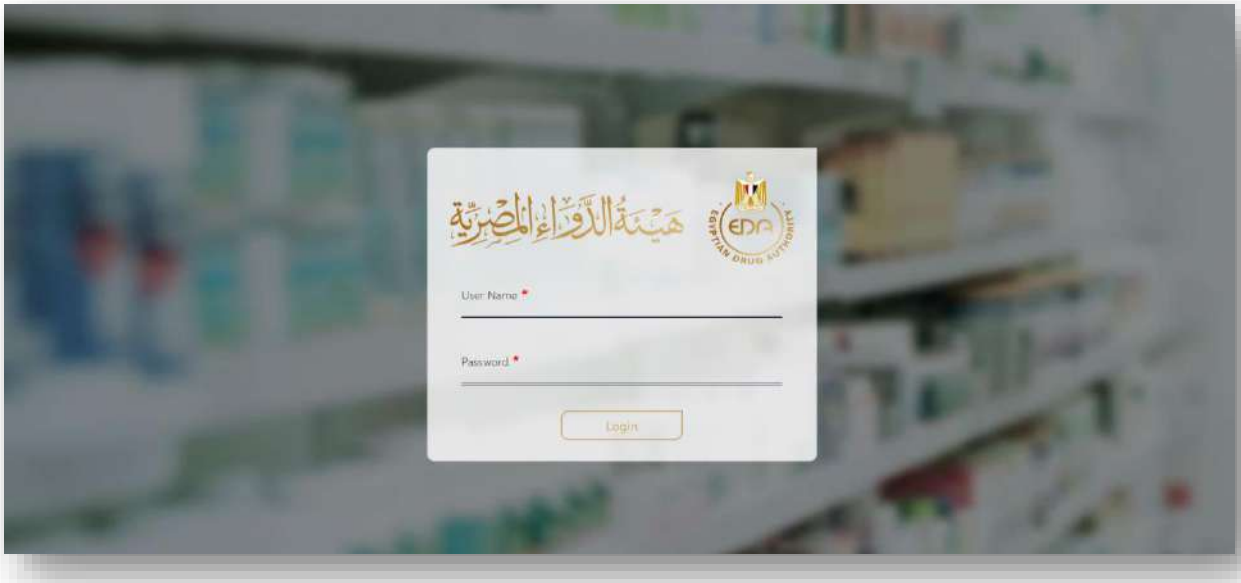
1- login screen

To login the portal , follow these steps :

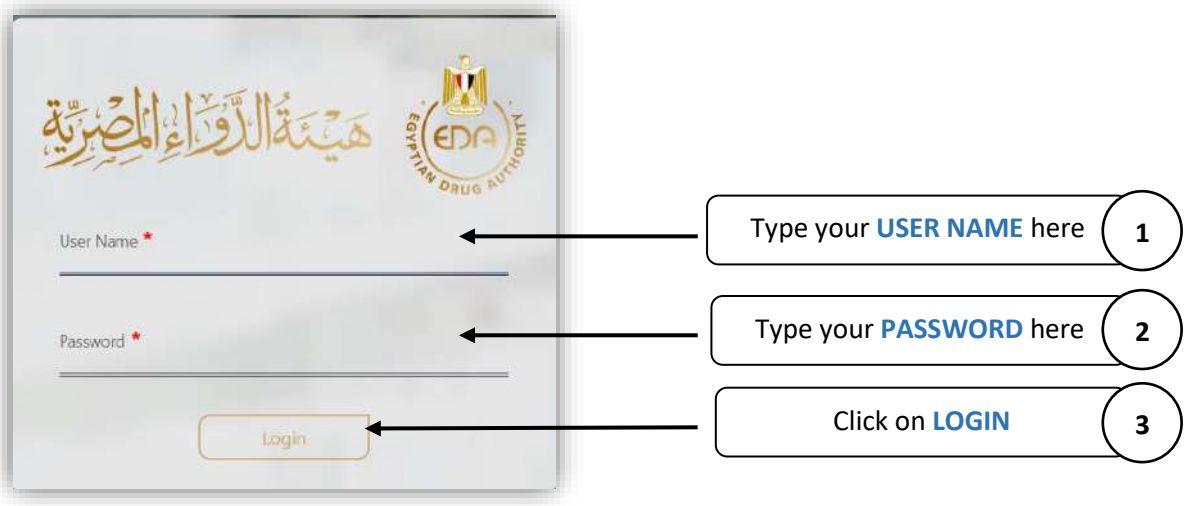
a) **User starts with internet browser prefer (mozilla firefox browser) then type the link:** https://egycosma.edaegypt.gov.eg



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

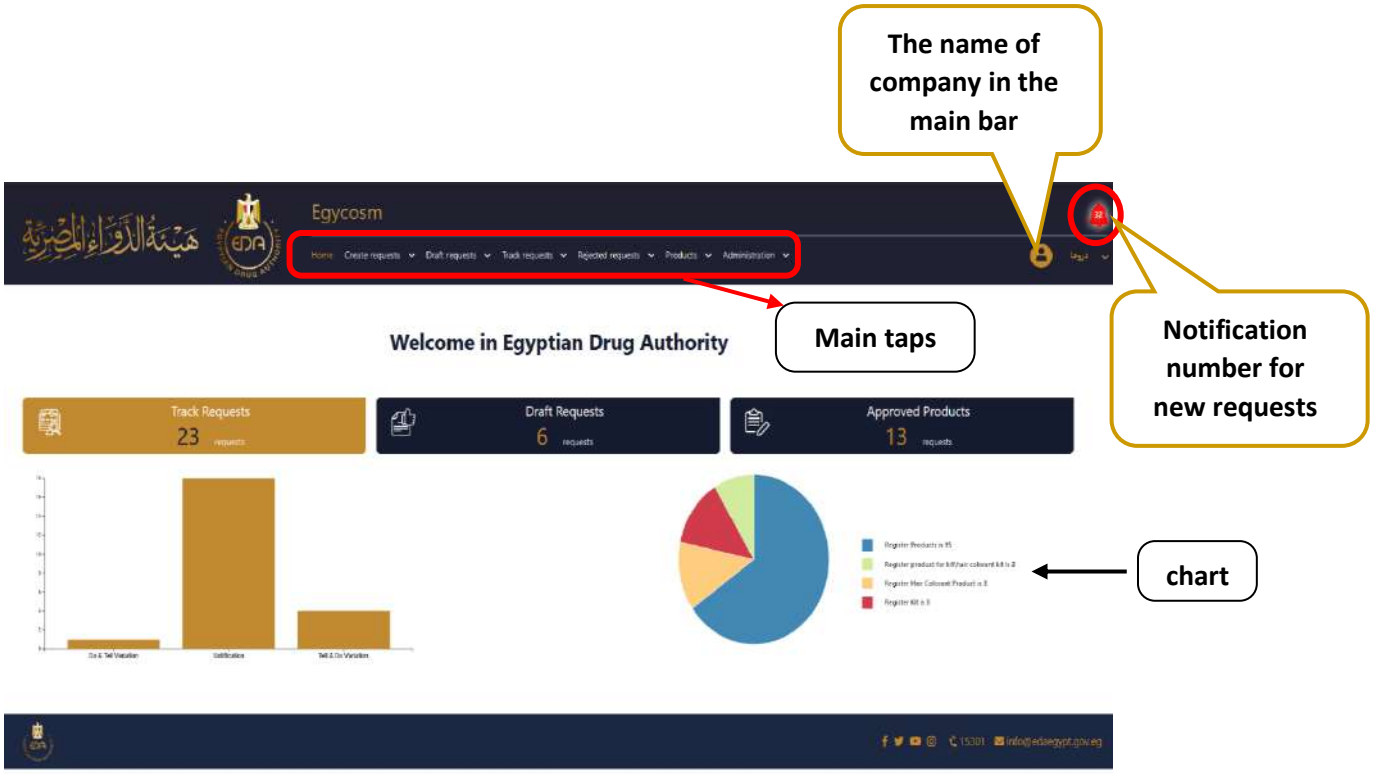


C) Type your pre delivered user name and password as shown down >



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

2- home page screen

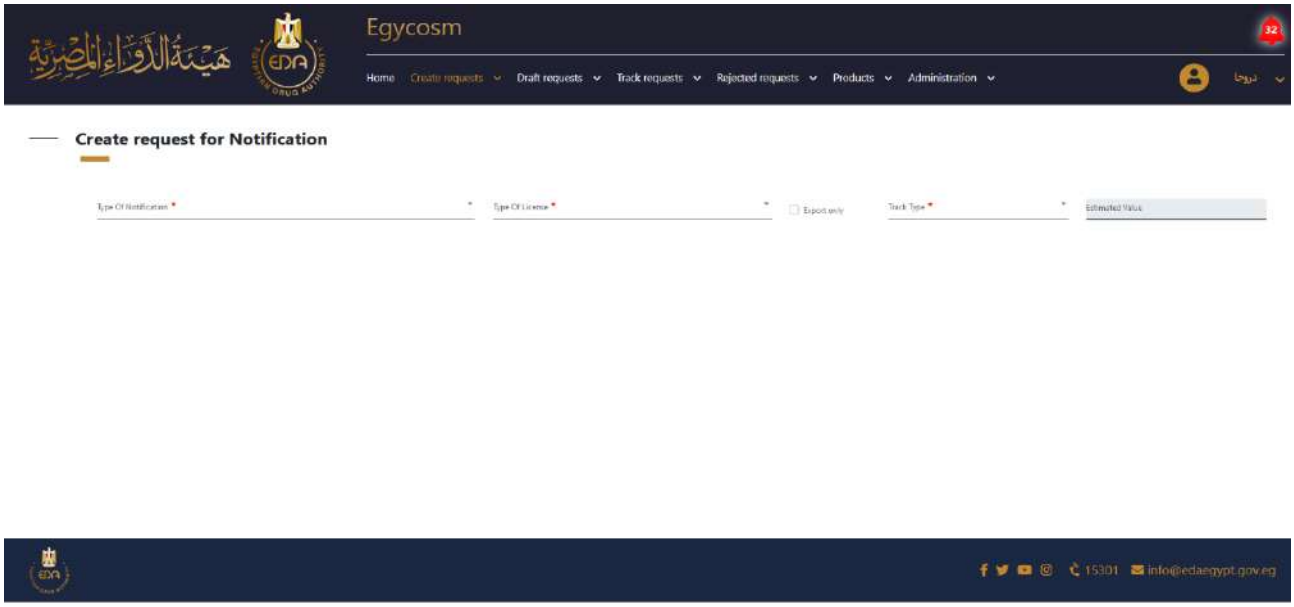


3- Create Request

To register a new request, follow these steps:

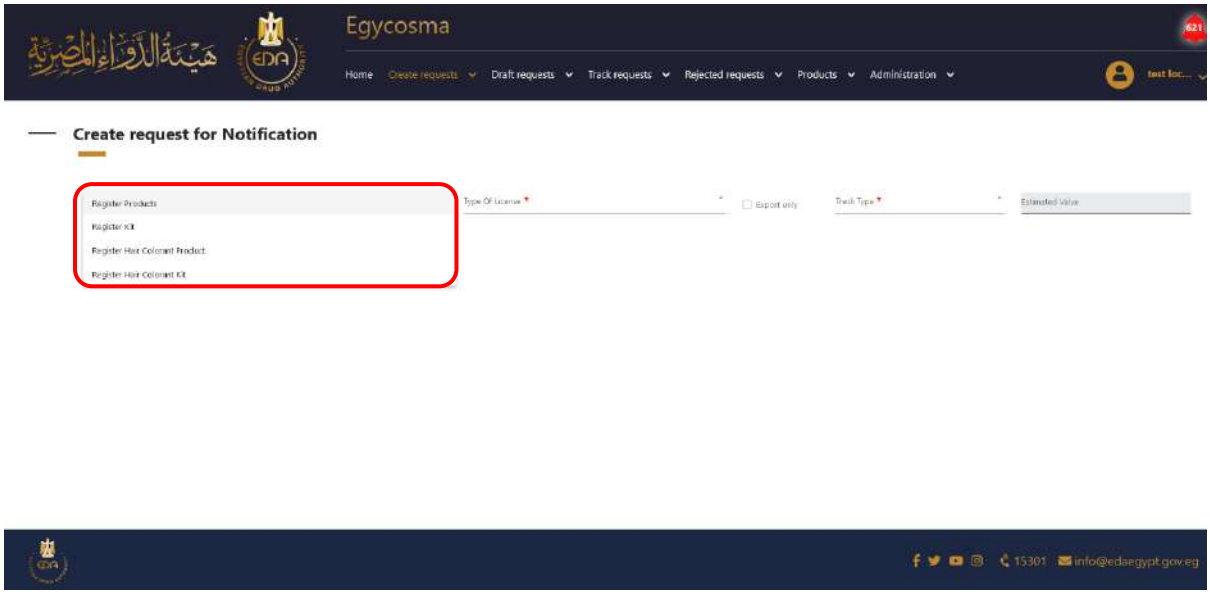
a) Open **Create requests tap** from the main tap as shown in the next picture then choose from the drop-down list **Notification**.

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

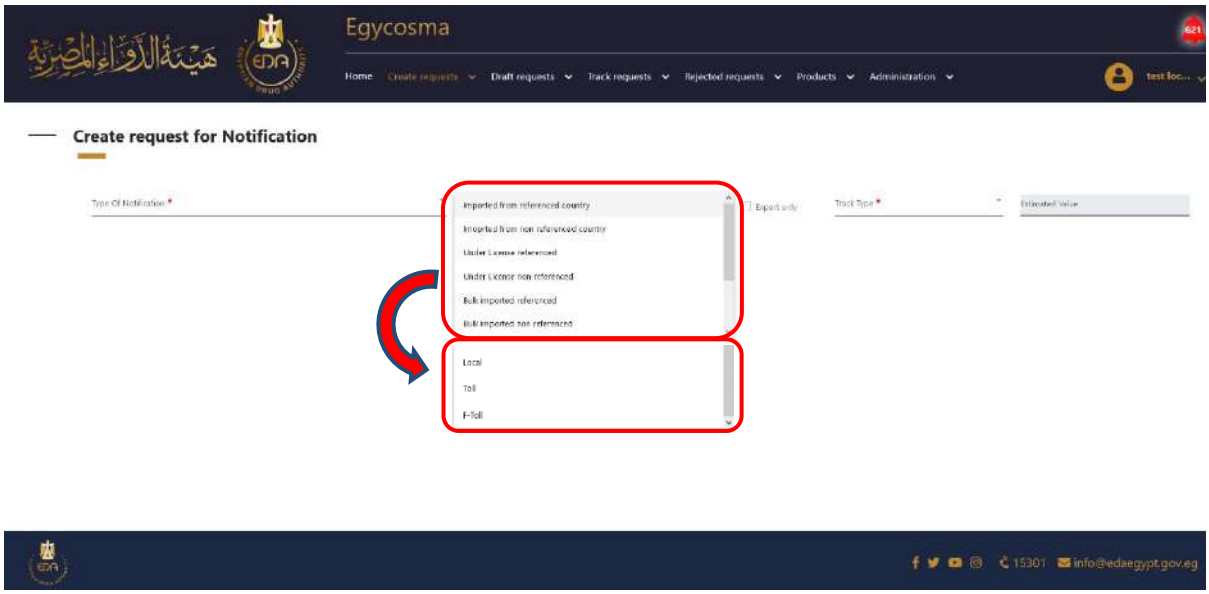


NOTE: All fields marked with an (*) are mandatory fields that must be filled, in order for the New Request to be saved and submit.

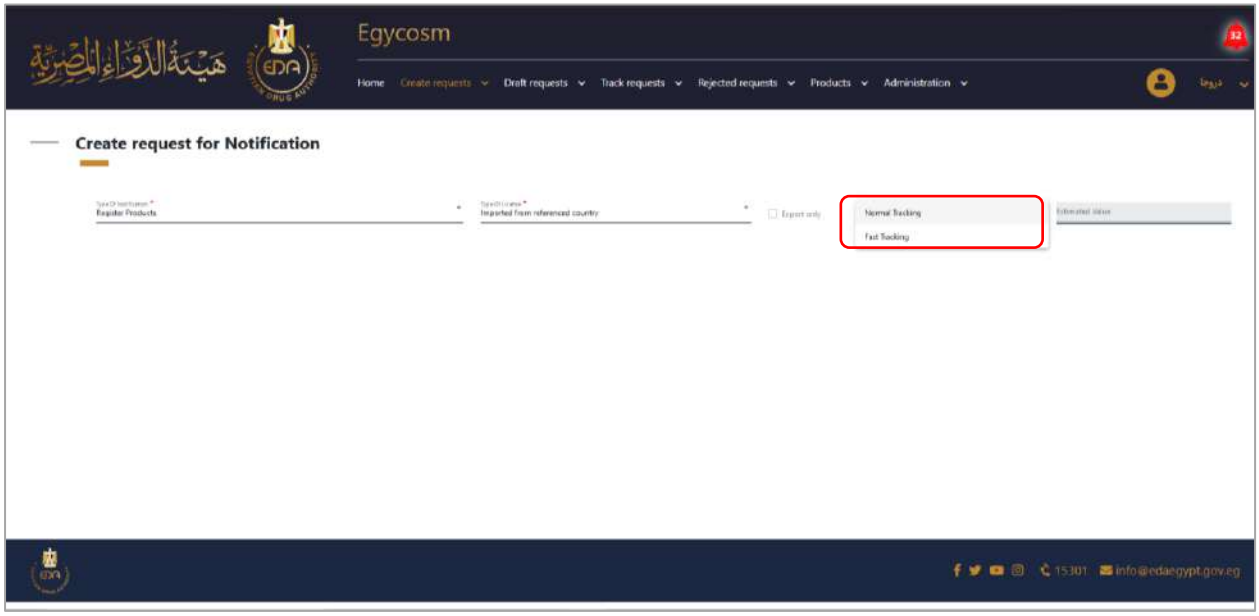
C) choose the type of the product that you want to register it from the drop-down list Type Of Notification field.



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.

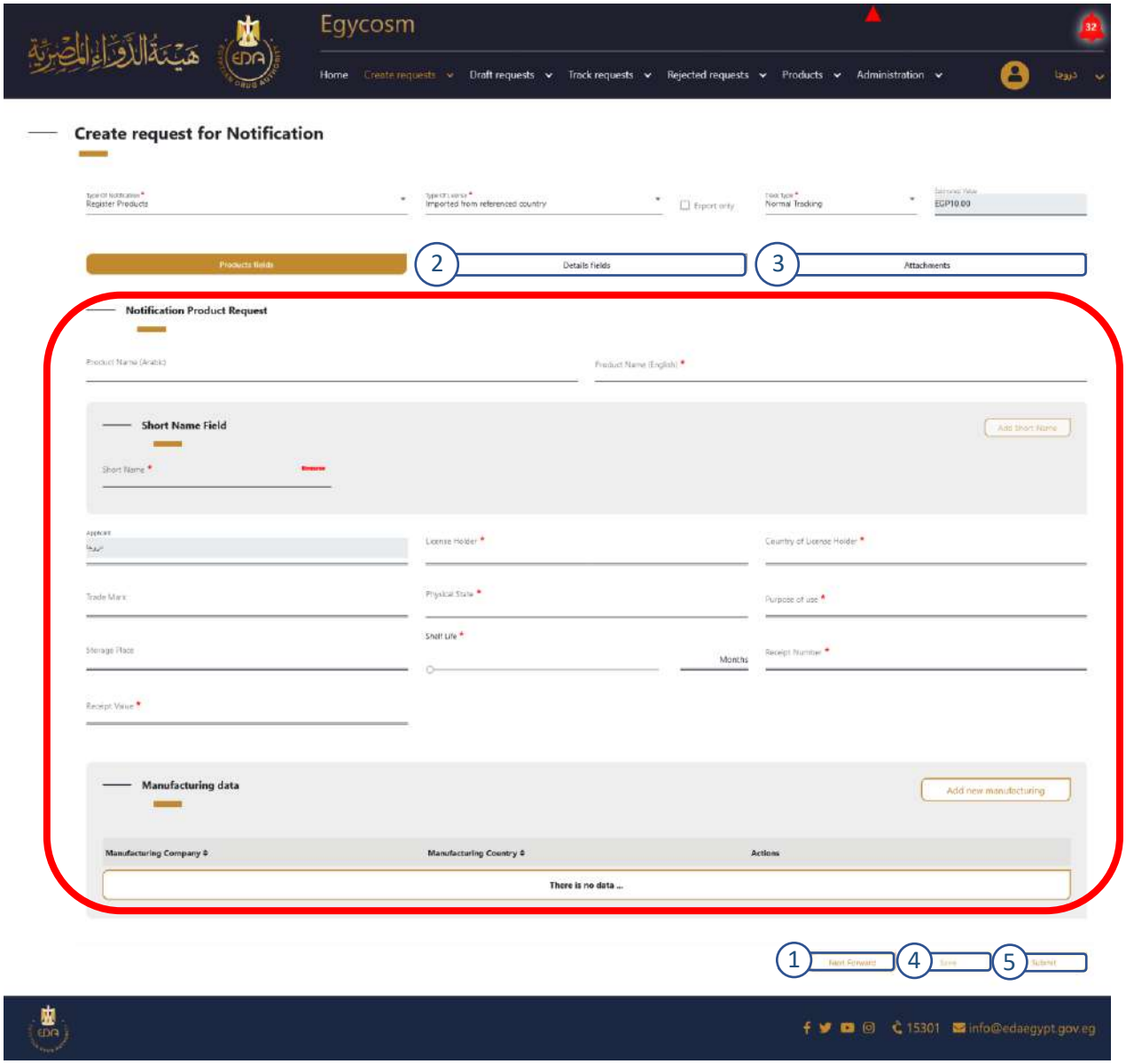


D) After choosing the type of notification, type of license and track type will appear the following:

1- estimated fee for this registration in the Estimated Value field.

2- all the required details about this registration that depends on the type of notification.

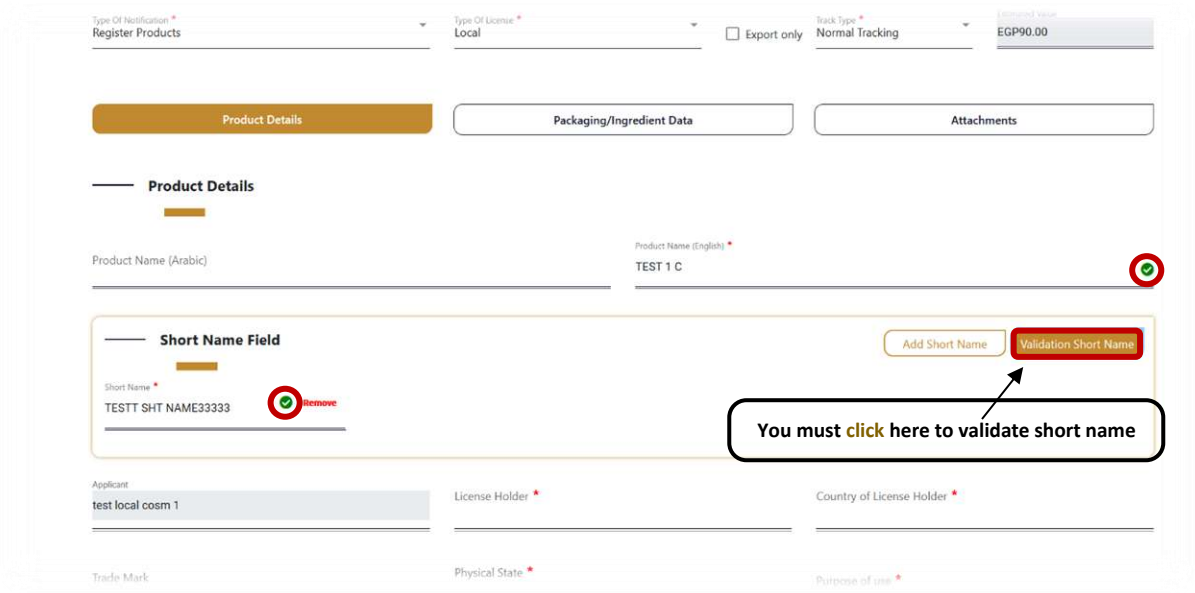
* In case the type of Notification is Register Product

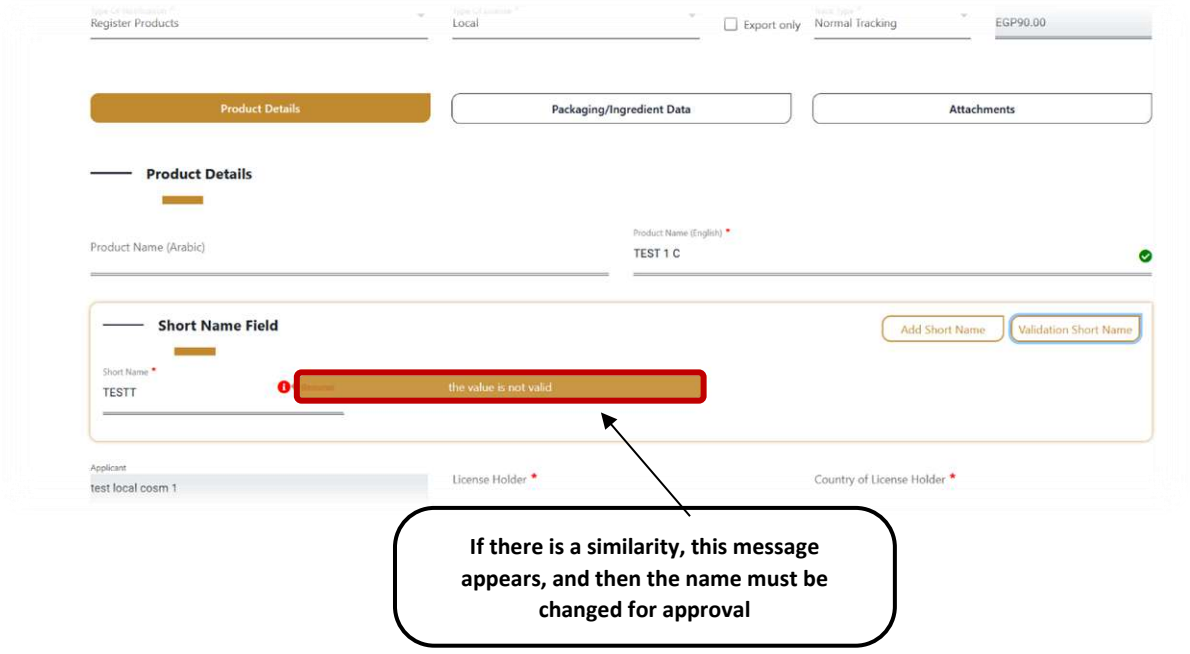


1- **The next forward button will transfer you to the next page(1) (details fields) or you can click directly on the details fields(2) tap or on the attachments(3)**

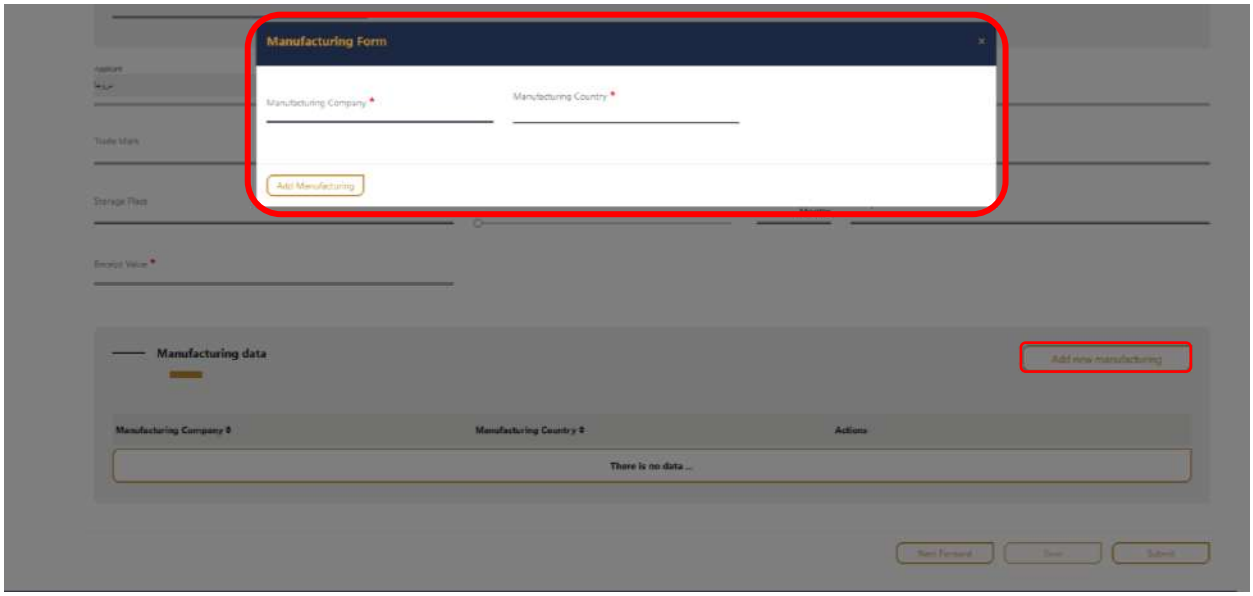
2- **after fill at least one filed with its custom data the save button(4) will be activated and the request will be saved in draft requests menu > notification tap until you complete all mandatory fields which have small red star on it (*) in the Type of Notification page , Type of license page and Track type page you can able to submit by clicking on submit buttom (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**





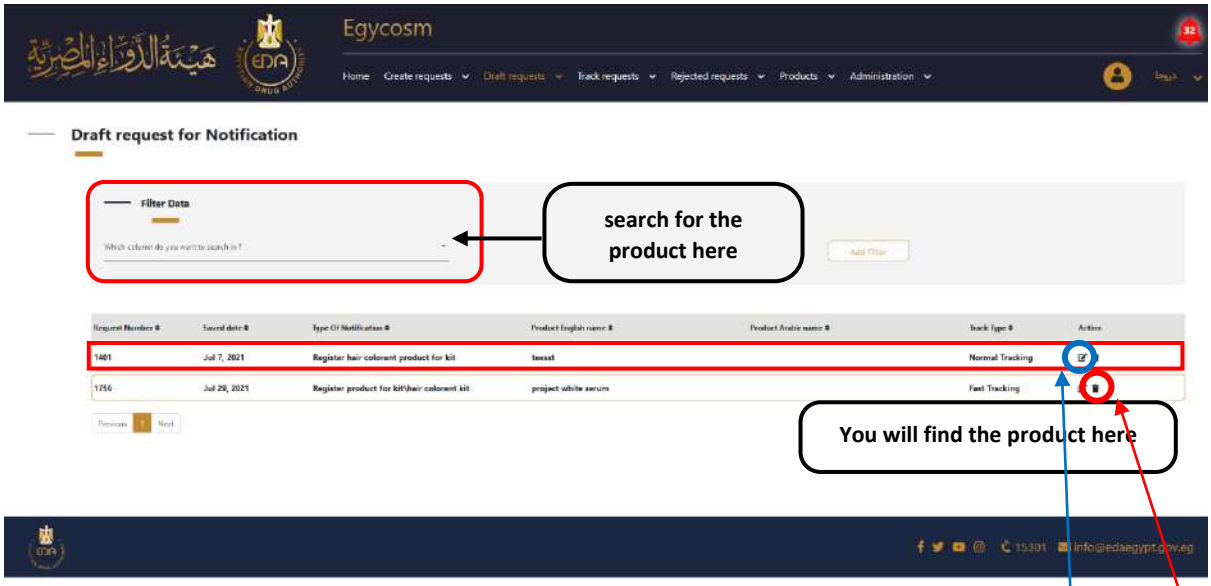
Click on add new manufacturing then a pop-up will appears including the form of manufacturing data Consists of:



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

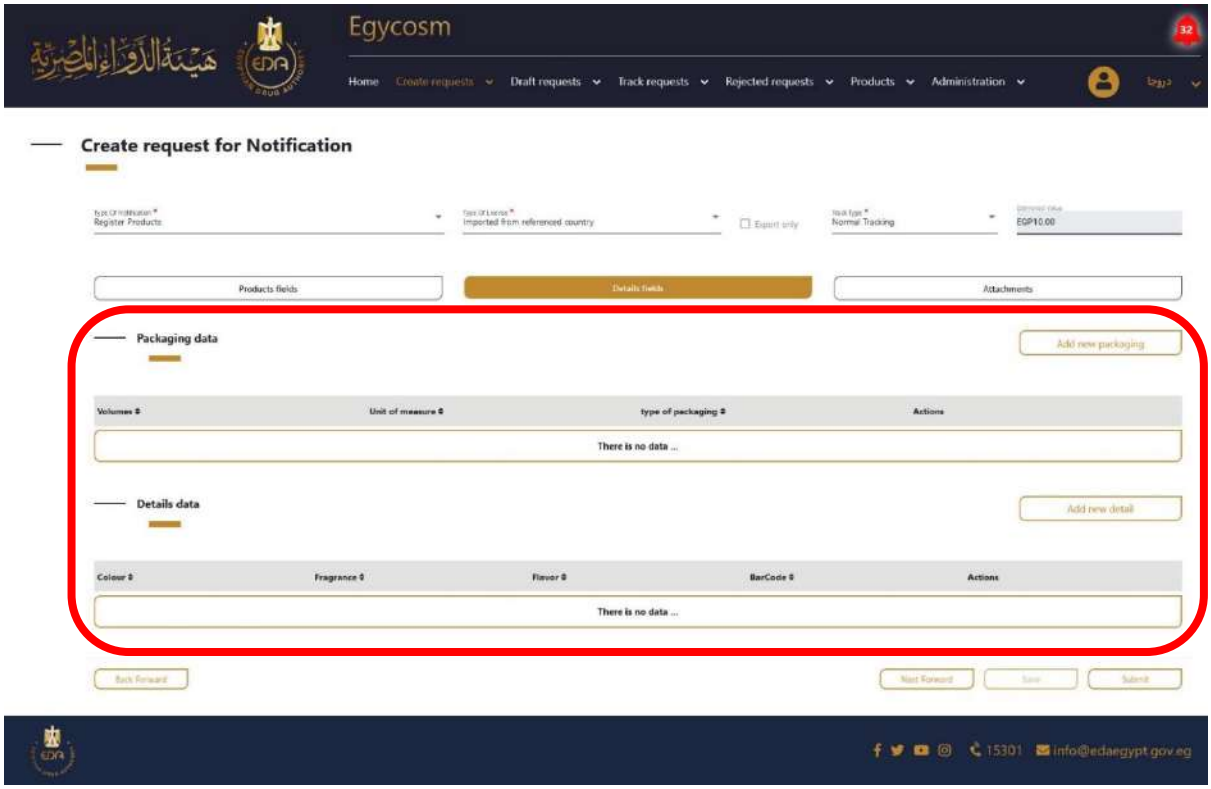
In order to make sure that the product has been saved and return to complete it again in anticipation of any technical malfunction

Draft requests > Notification page

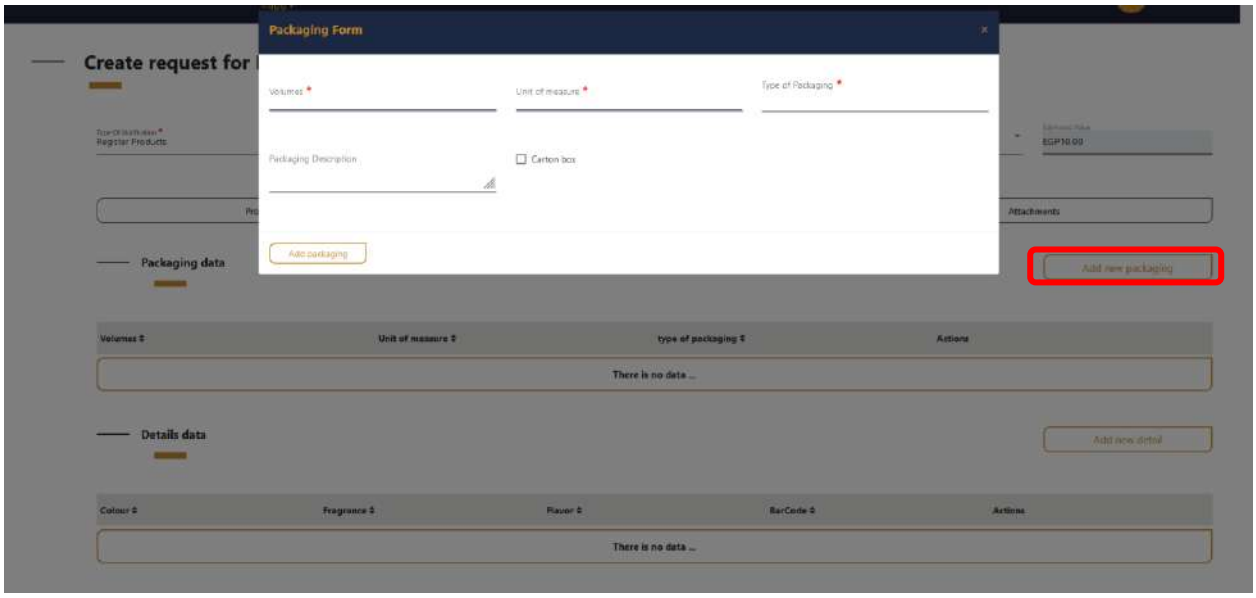


Then you can go back to complete your request by clicking on edit sign
Or remove the request from draft by clicking on delete sign

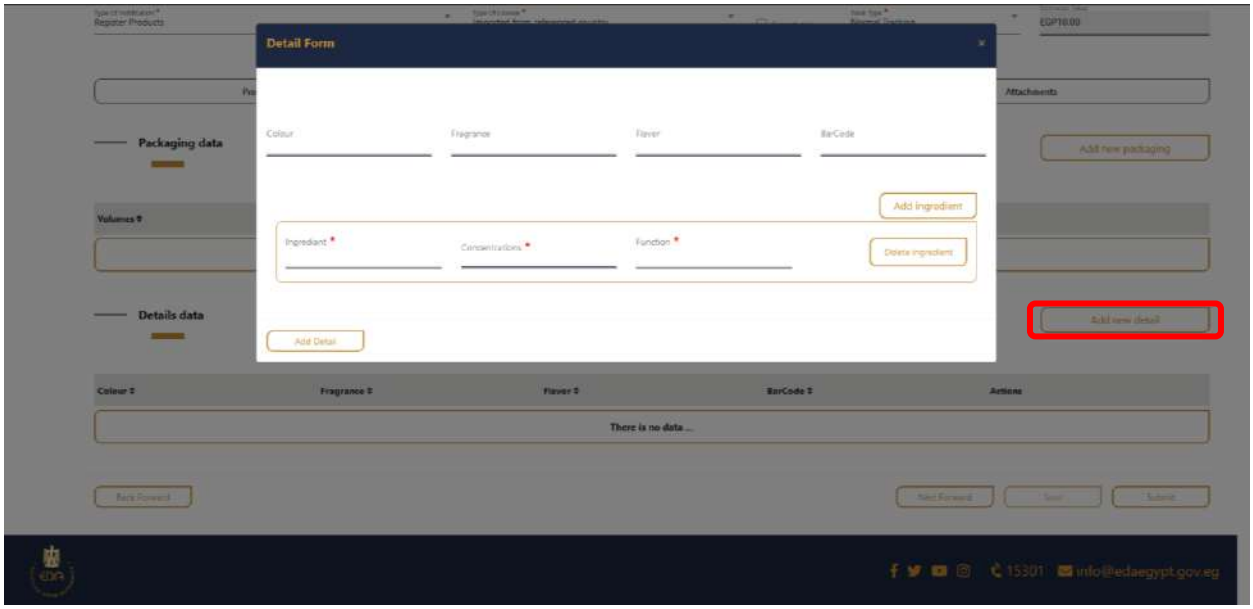
1- The tap of Details fields is divided into two parts packaging data , Details data



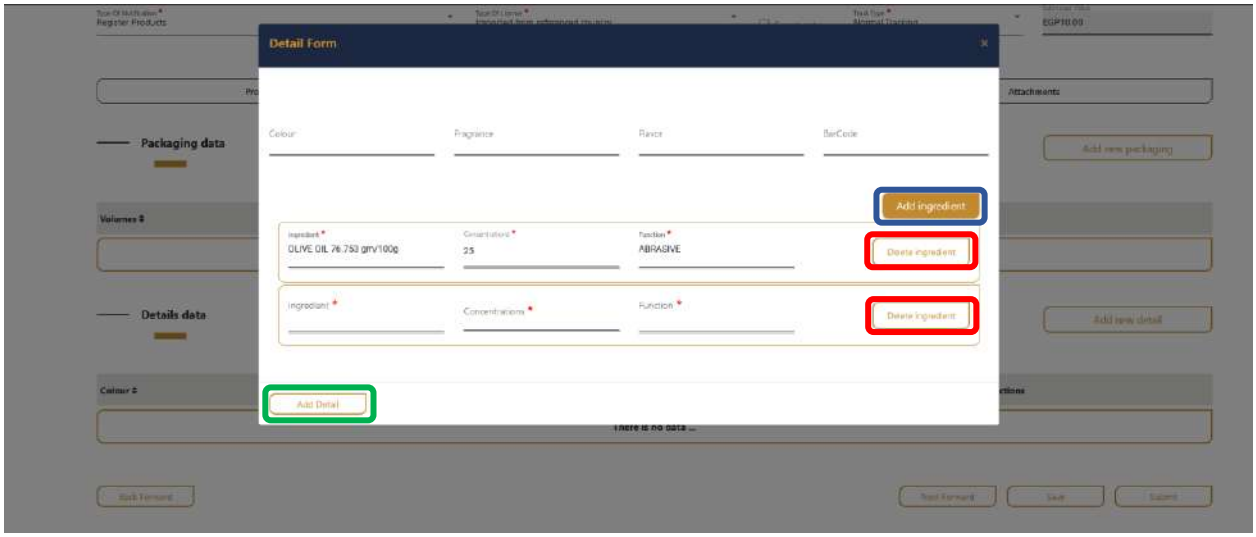
Click on add new add new packaging then a pop-up will appears including The form of packaging data Consists of

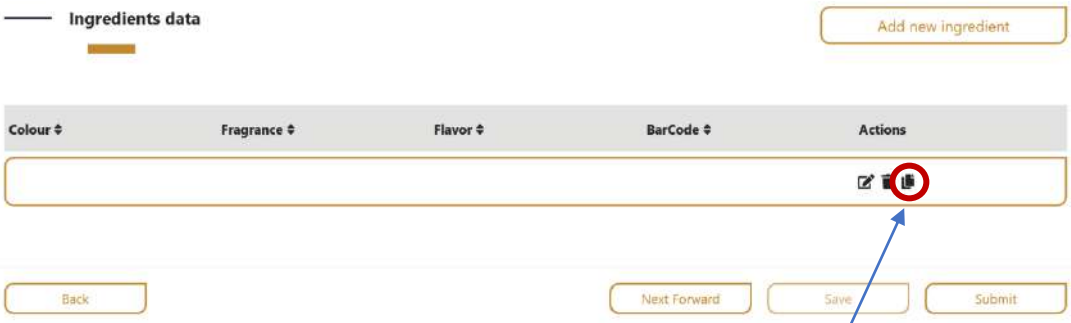


Click on add new add new detail then a pop-up will appears including the form of details data Consists of



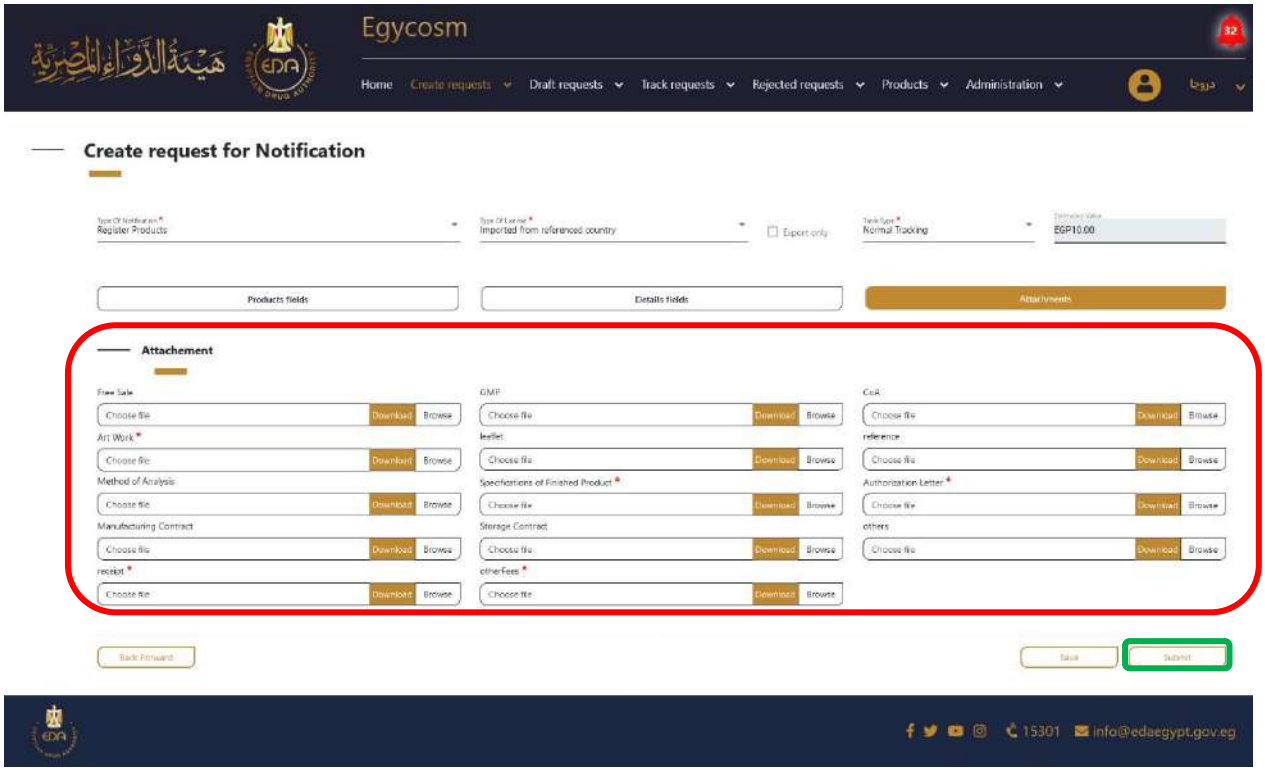
You can add many ingredients or delete them from those buttons and after finishing this step click on add details button





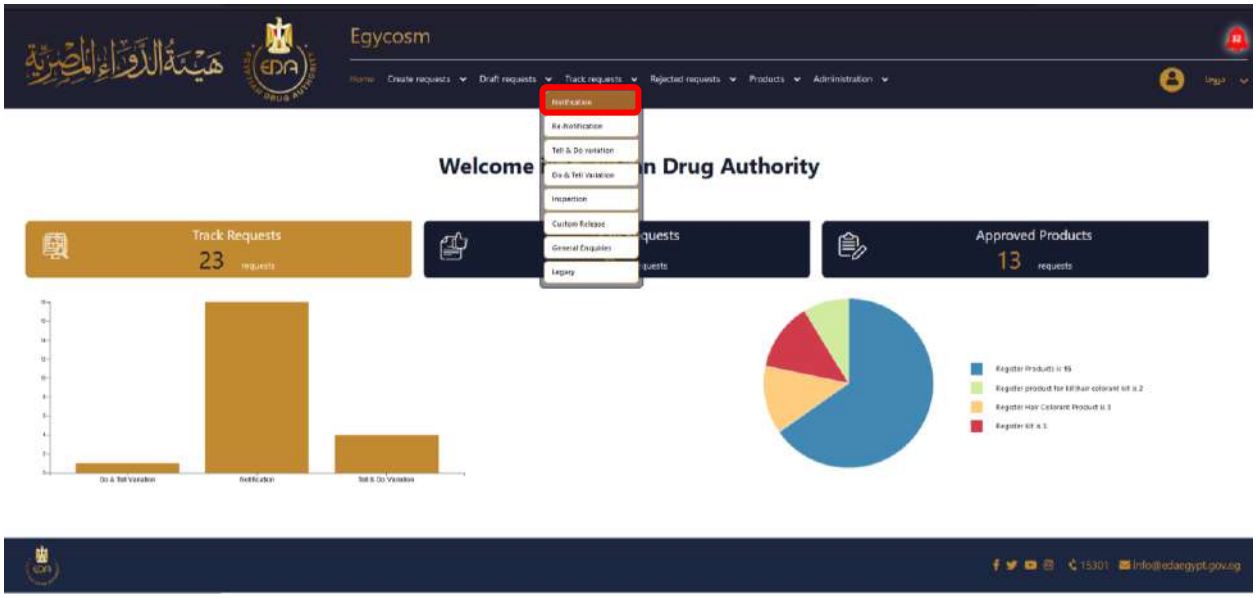
If there are similar ingredient data, you can press a copy button instead of rewriting

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)

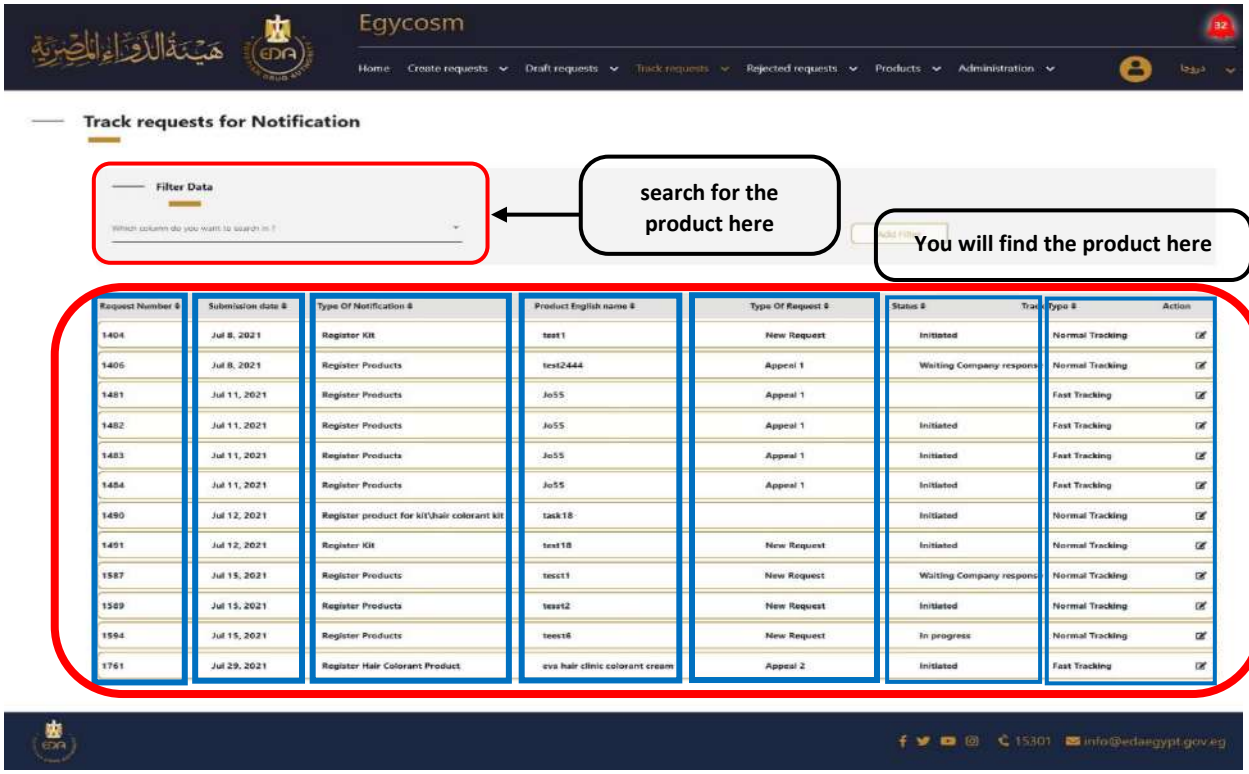


1- **At the end you make sure that all the mandatories fields are filled with its costume data then click on Submit button**

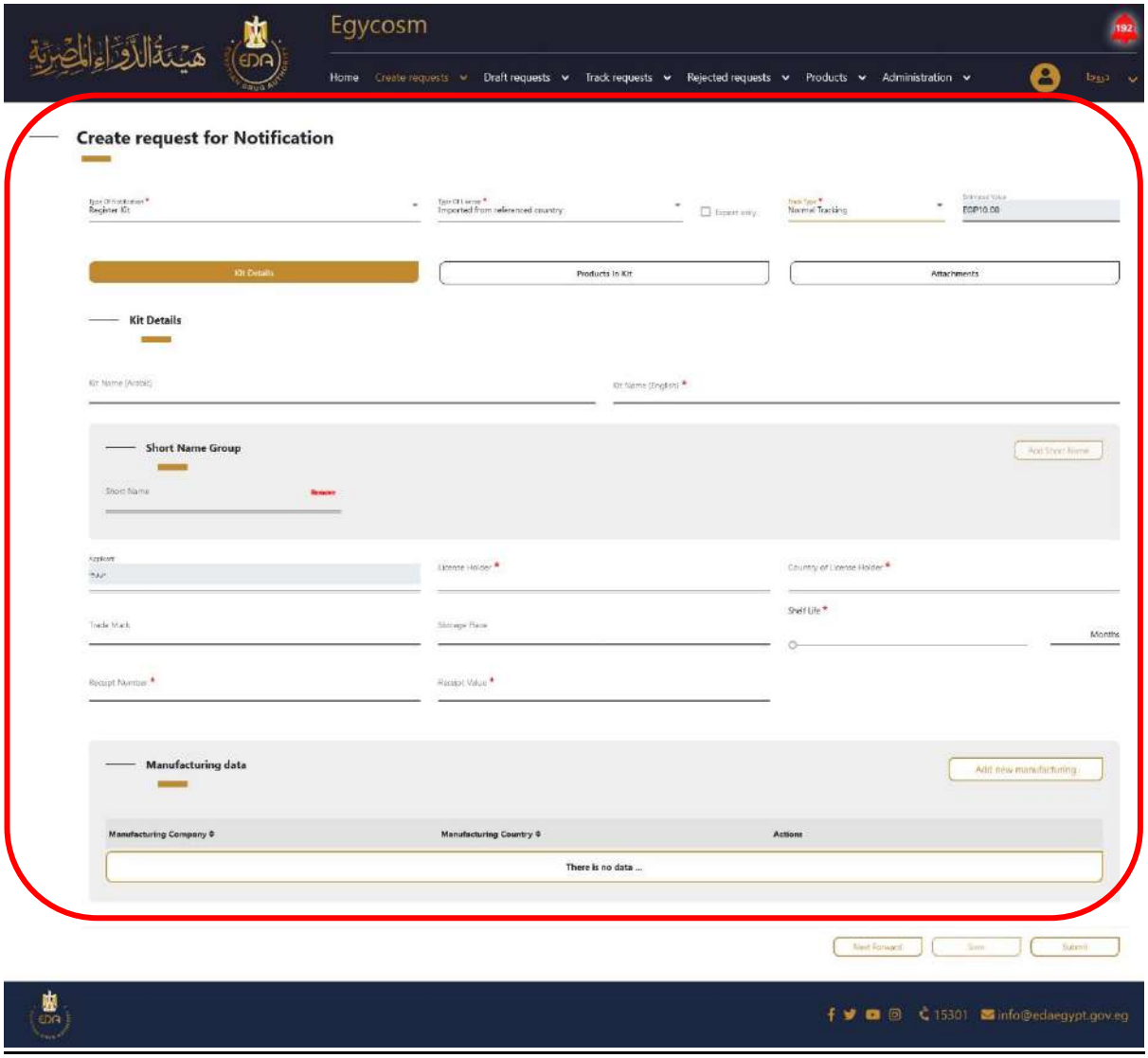
After you have finished entering all the data for the product and press submit then the product will go directly to Track requests > Notification



At the Track requests for Notification page there was a 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

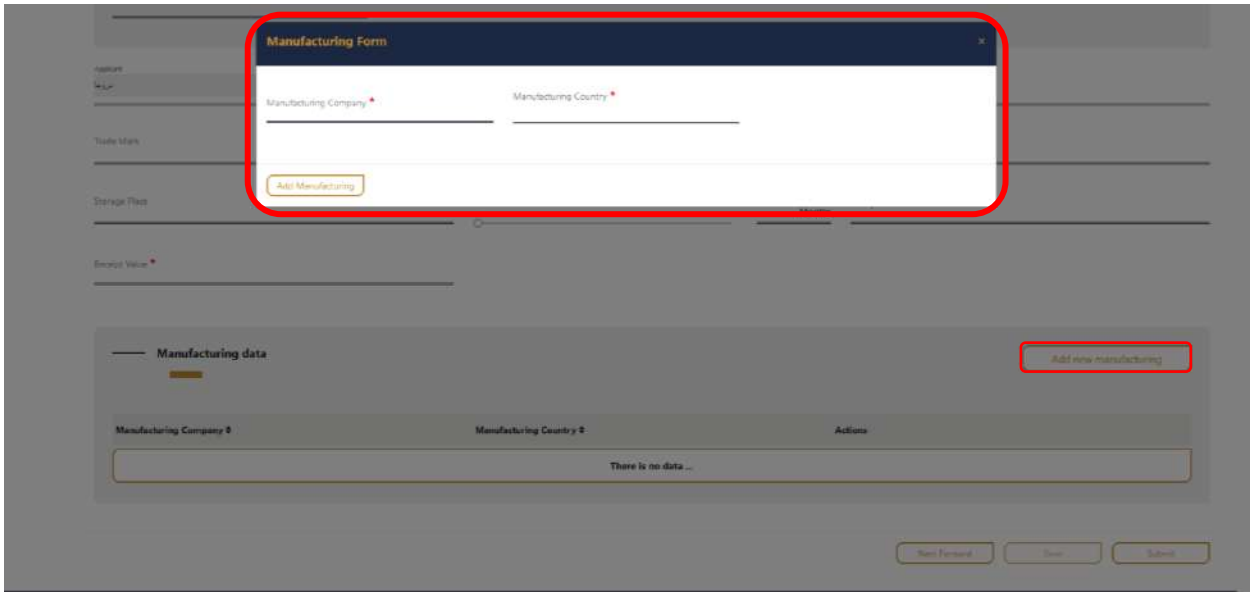


*** In case the type of Notification is Register Kit**



2- after fill at least one filed 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 the Type of Notification page , Type of license page and Track type page you can able to submit by clicking on submit buttom and the request will transfer to track requests menu > notification tap.

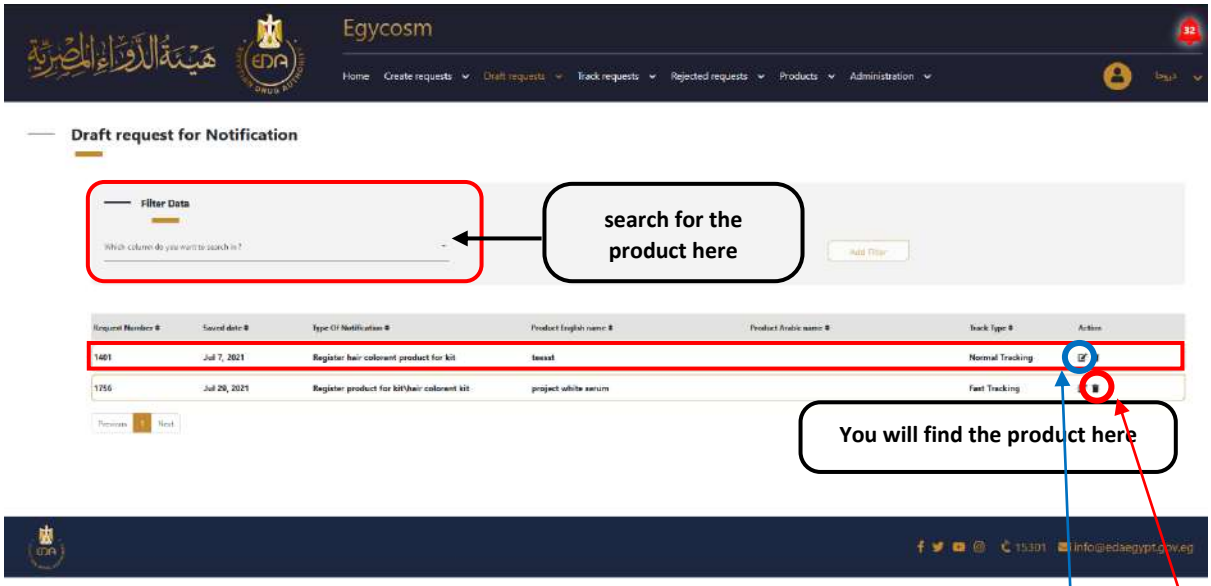
Click on add new manufacturing then a pop-up will appears including the form of manufacturing data Consists of:



3- 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

Draft requests > Notification page

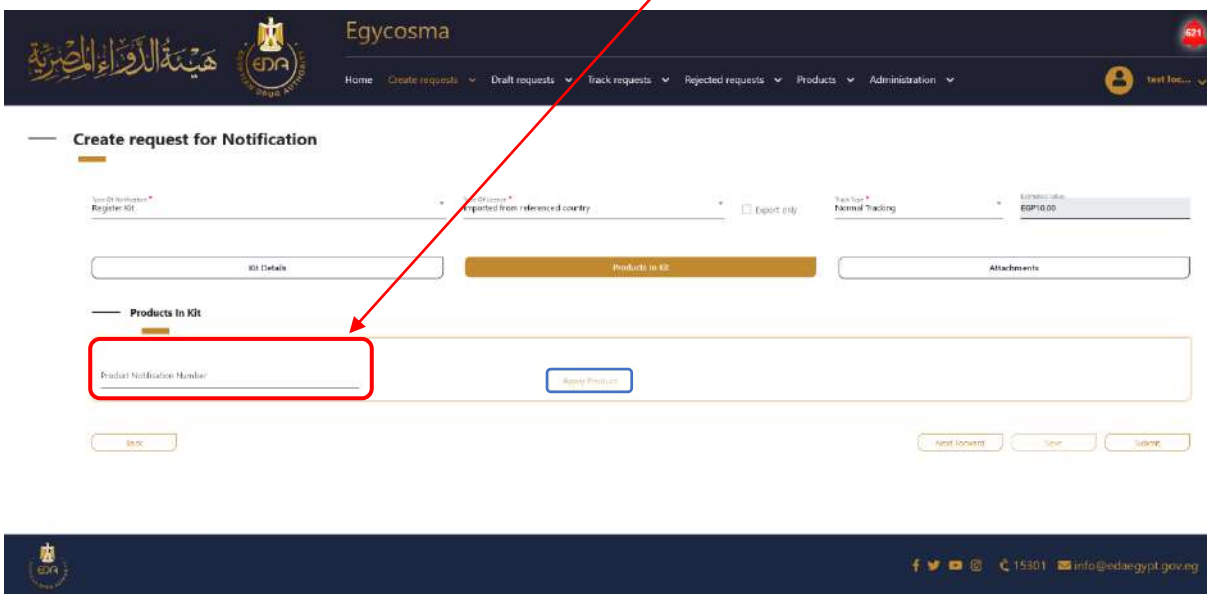


Then you can go back to complete your request by clicking on edit sign
Or remove the request from draft by clicking on delete sign

❖ **The tap of Product in Kit page choose the product status is approved products**

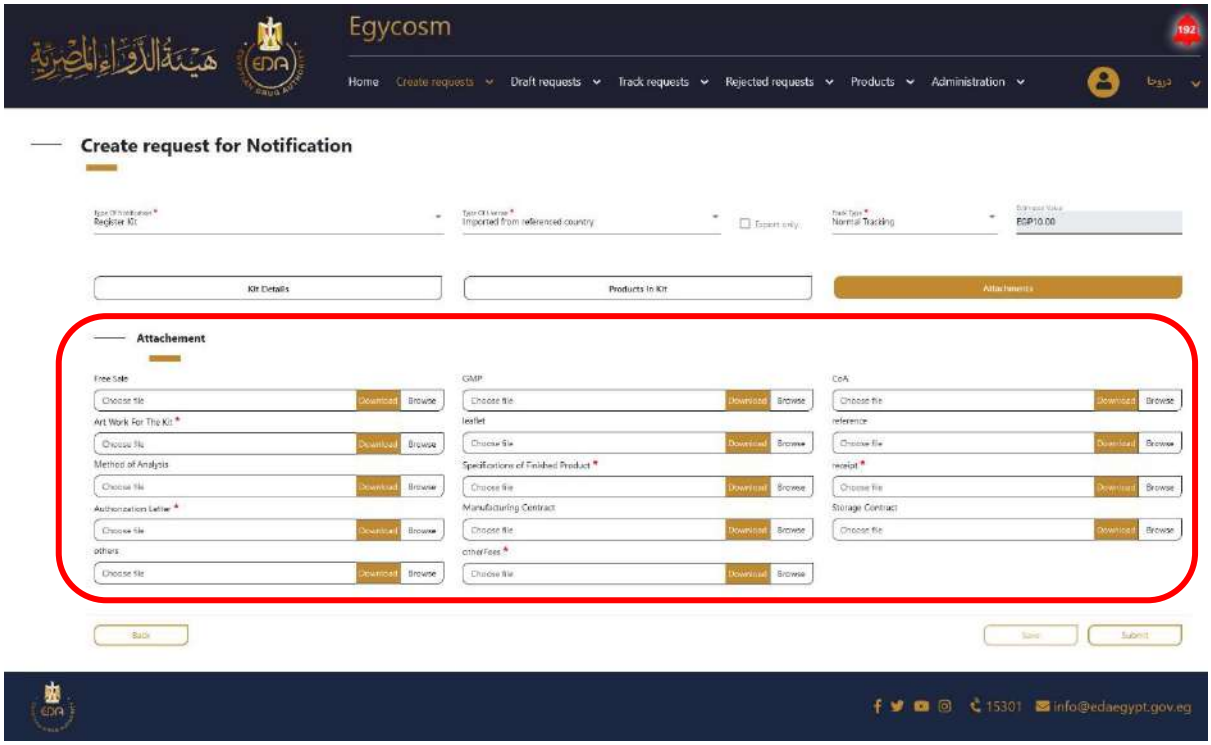
When choose the product from approved products

Type the notification number of the product here



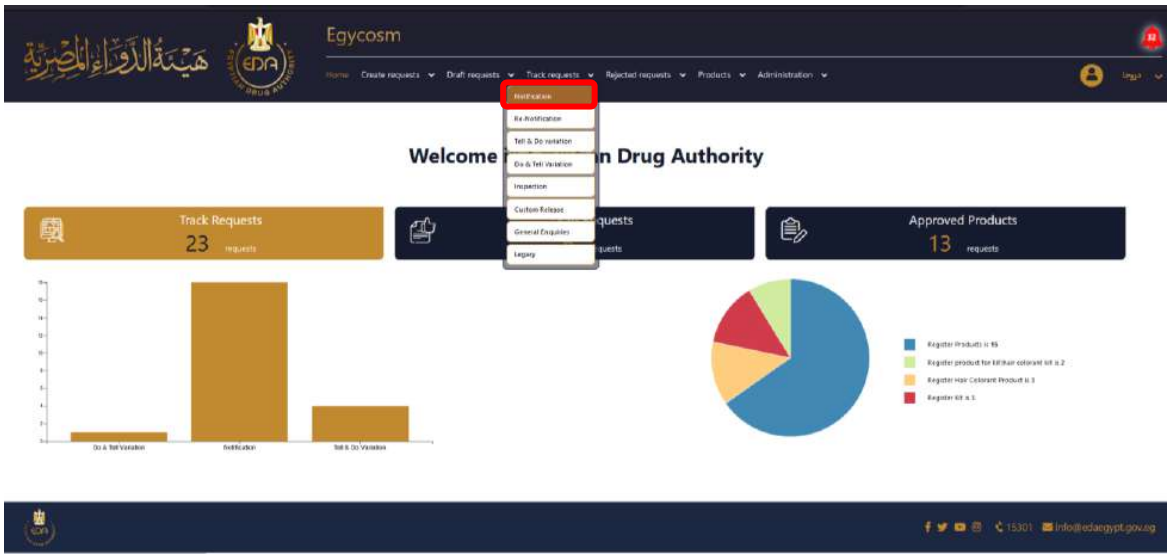
Then click on Apply Product button

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)

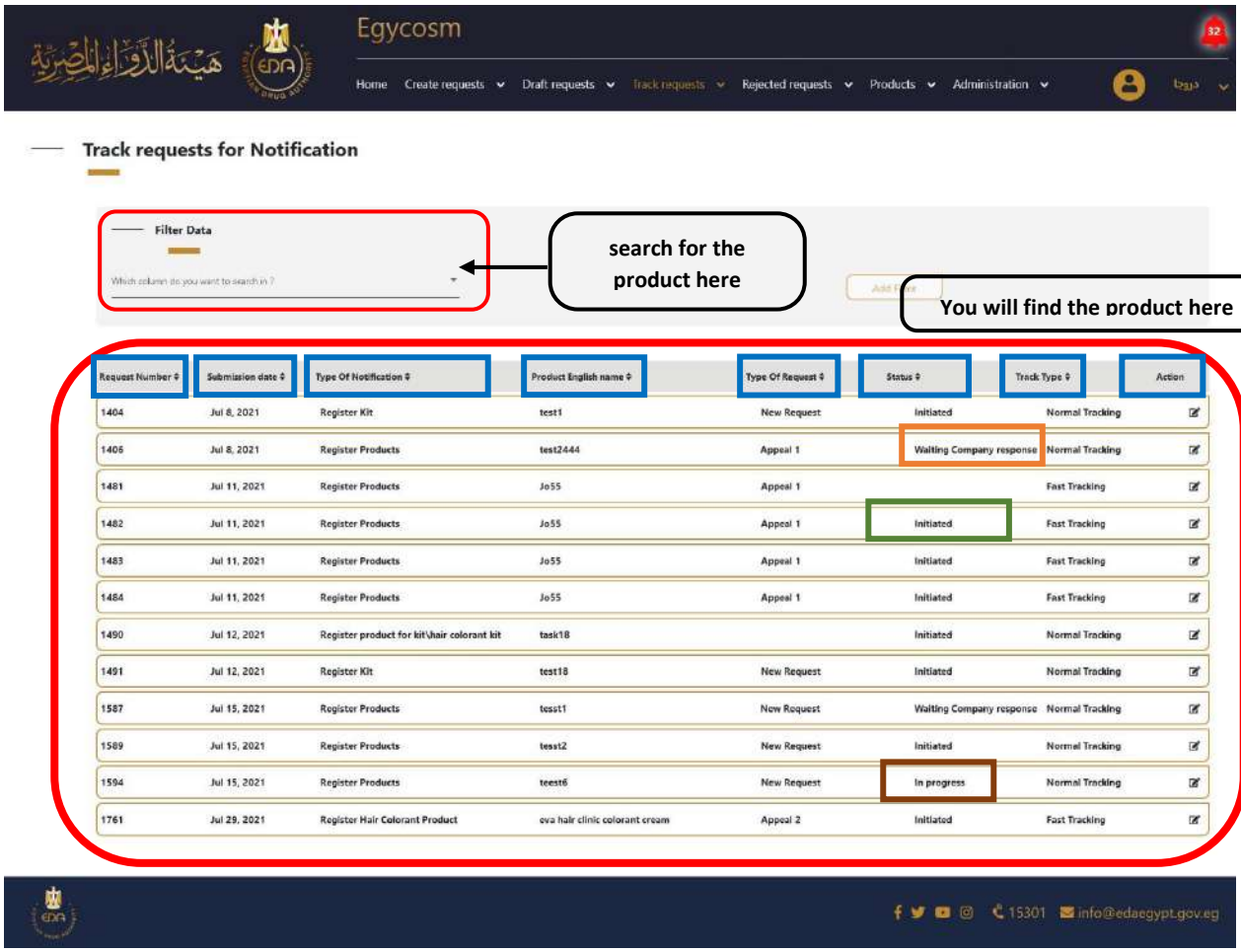


- **At the end you make sure that all the mandatories' fields are filled with its costume data then click on Submit button**

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



At the Track requests for Notification page there was a 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



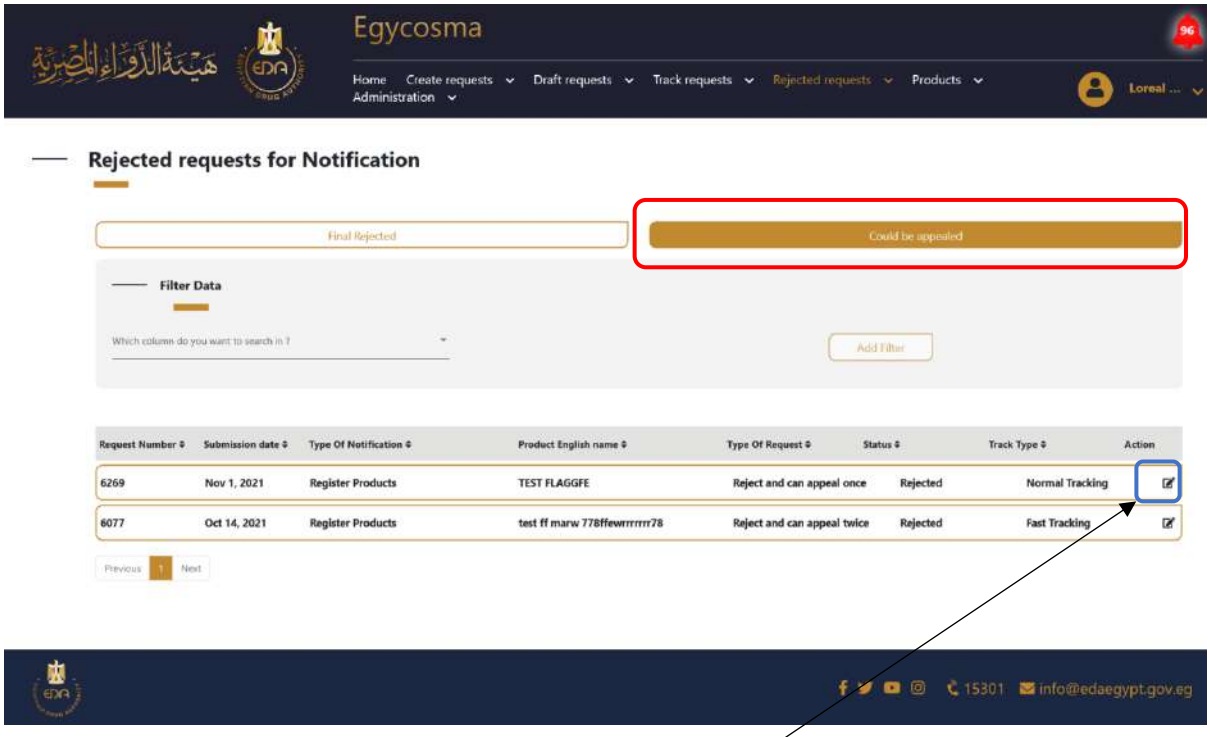
6- When you submit the request status updated to Initiated

7- In case you get first comment from the authority status updated to waiting company response and you need to replay comments you got and re-submit the request

8- when you re-submit request status 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.**



By clicking on the action icon here, the page will be transferred to Create requests for Notification, as appearing in the picture in the next page.

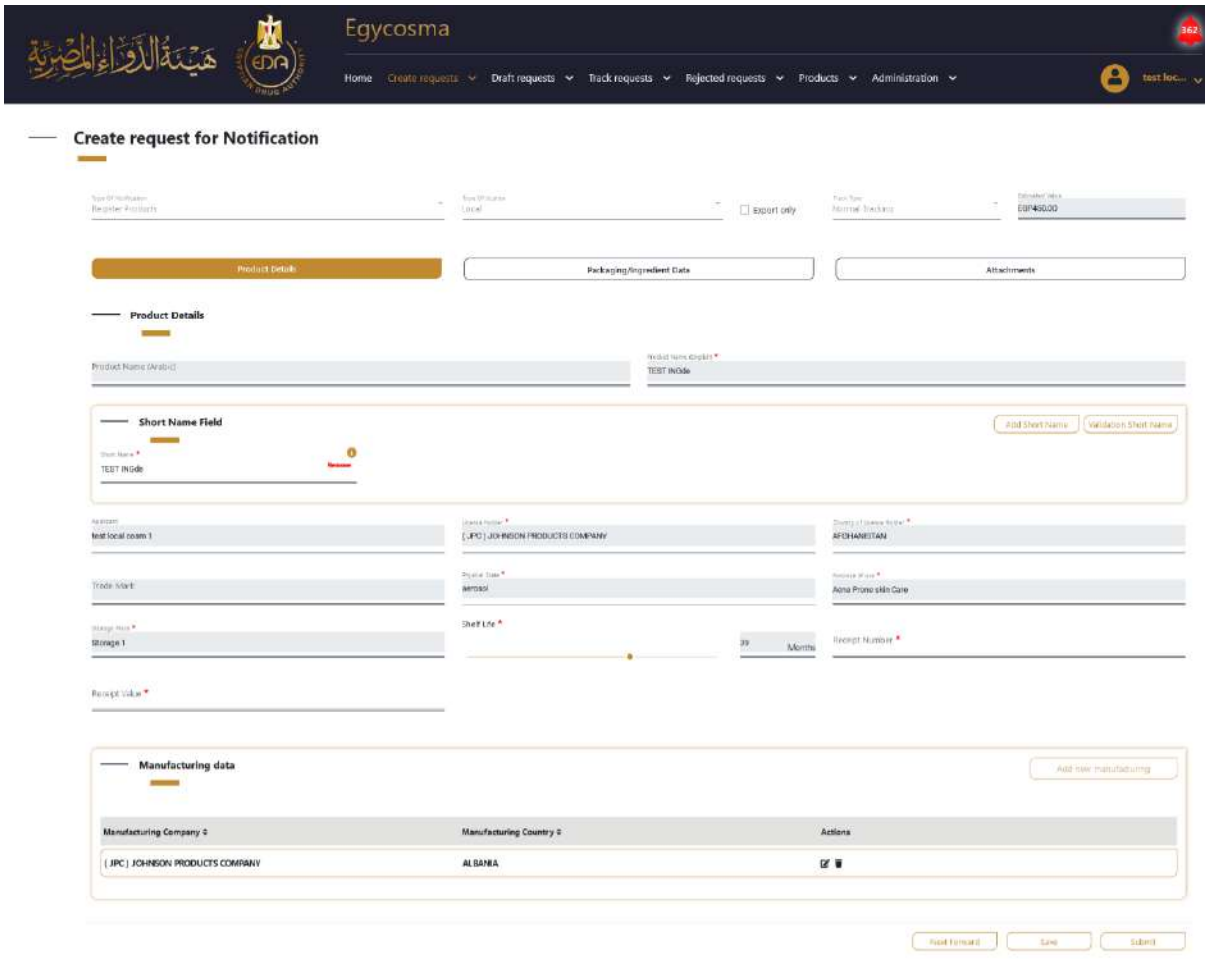
Request Number	Submission date	Type Of Notification	Product English name	Type Of Request	Status	Track Type	Action
5128	Sep 12, 2021	Register Products	test sH	Reject and can appeal once	Rejected	Normal Tracking	
5099	Sep 12, 2021	Register Products	test V1	Reject and can appeal twice	Rejected	Normal Tracking	
4878	Sep 7, 2021	Register Products	test reject reason 1	Reject and can appeal twice	Rejected	Normal Tracking	

Request id : 4878
Submission date : Sep 7, 2021
Type Of Notification : Register Products
Product English name : test reject reason 1
Type Of Request : Reject and can appeal twice
Status : Rejected
Track Type : Normal Tracking
Reject Reasons :
1. تحتوي على بيانات غير مطابقة او غير صحيحة
2. منتهى الصلاحية

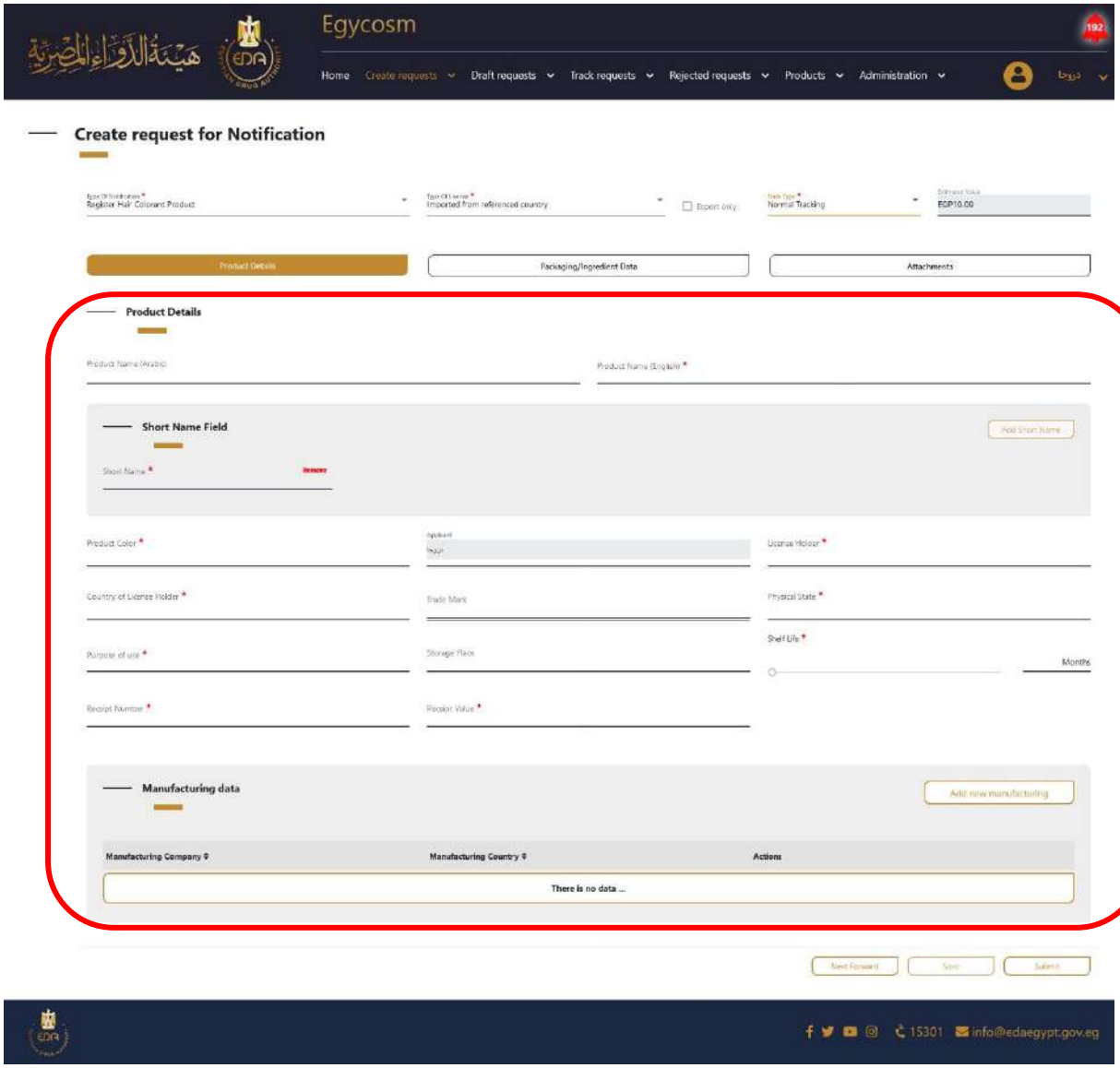
4725	Sep 3, 2021	Register Products	test 555	Reject and can appeal twice	Rejected	Normal Tracking	
4705	Sep 2, 2021	Register Products	test	Reject and can appeal twice	Rejected	Normal Tracking	
4488	Sep 1, 2021	Register Products	TEST 88	Reject and can appeal once	Rejected	Normal Tracking	
4157	Aug 30, 2021	Register Products	test 756	Reject and can appeal twice	Rejected	Normal Tracking	

Previous 1 2 Next

If you click on any product, you can see the reject reason here

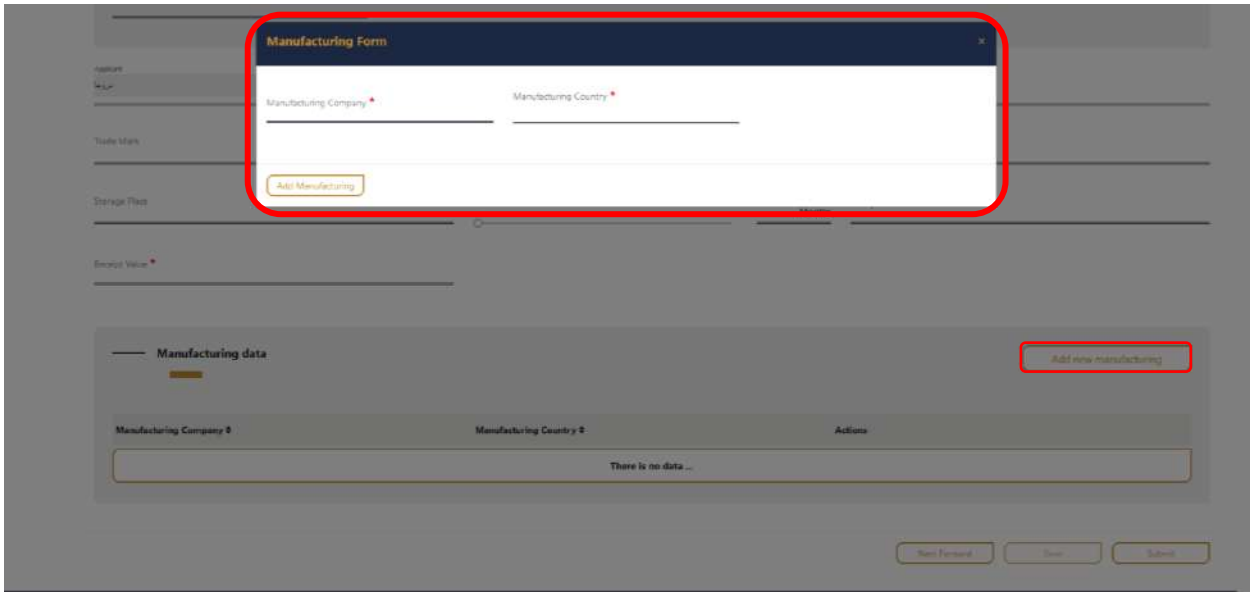


* In case the type of Notification is Register Hair Colorant Product



- **after fill at least one filed 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 the Type of Notification page , Type of license page and Track type page you can able to submit by clicking on submit buttom and the request will transfer to track requests menu > notification tap.**

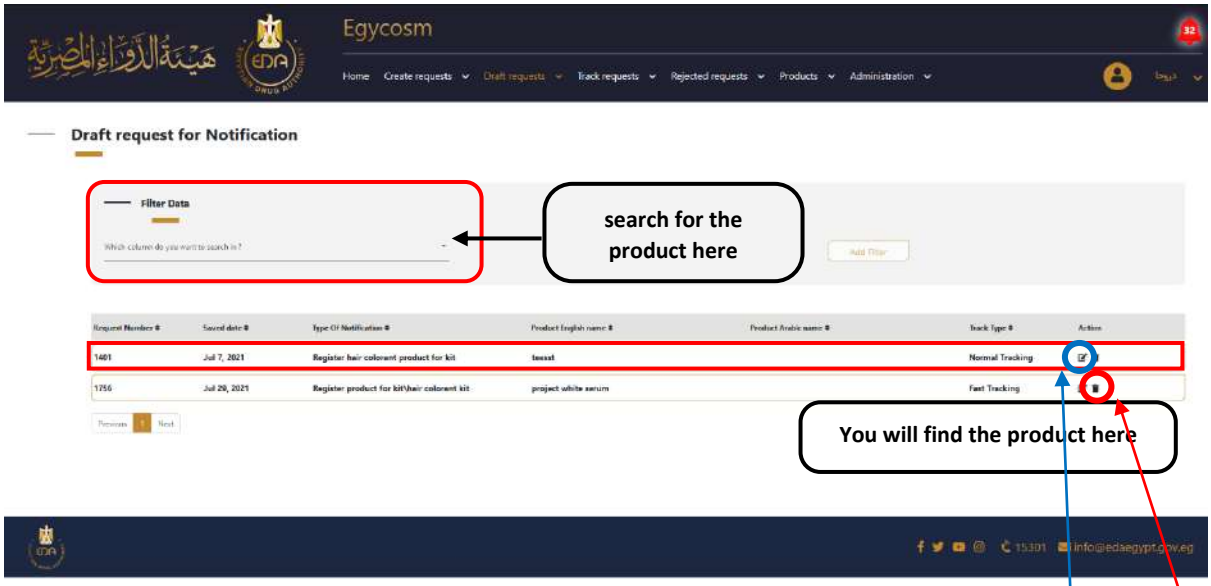
Click on add new manufacturing then a pop-up will appears including the form of manufacturing data Consists of:



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

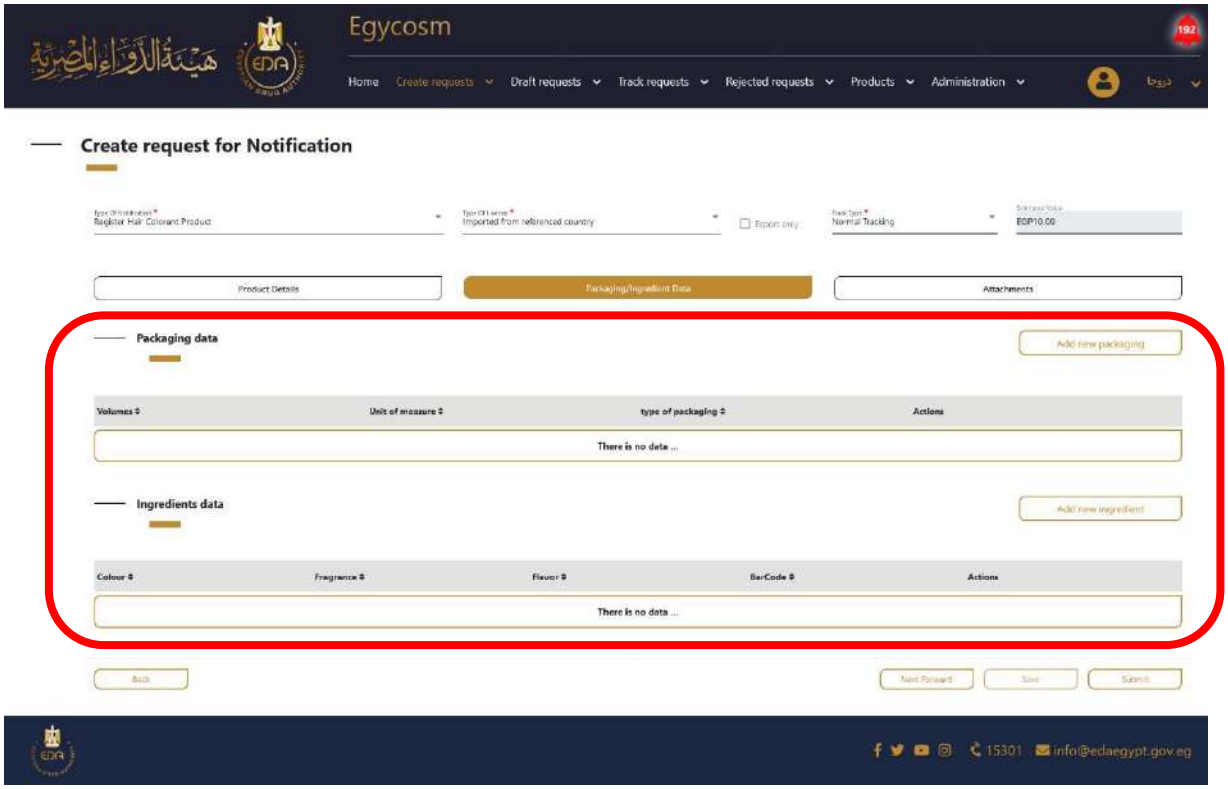
In order to make sure that the product has been saved and return to complete it again in anticipation of any technical malfunction

Draft requests > Notification page

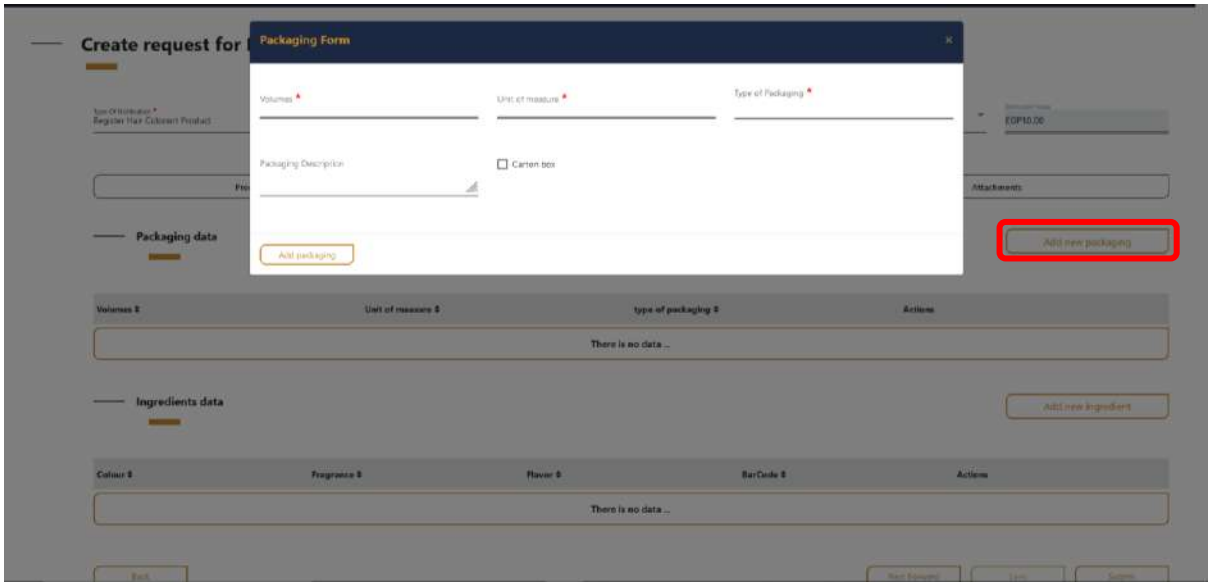


Then you can go back to complete your request by clicking on edit sign
Or remove the request from draft by clicking on delete sign

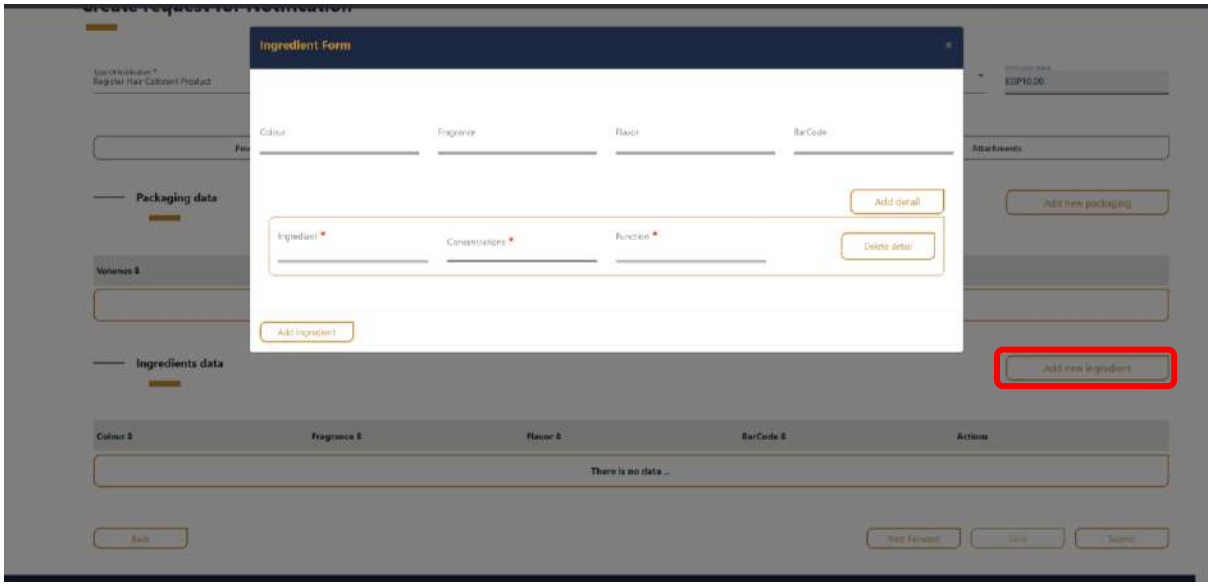
❖ **The tap of Packaging/Ingredient Data is divided into two parts packaging data , Ingredient data**



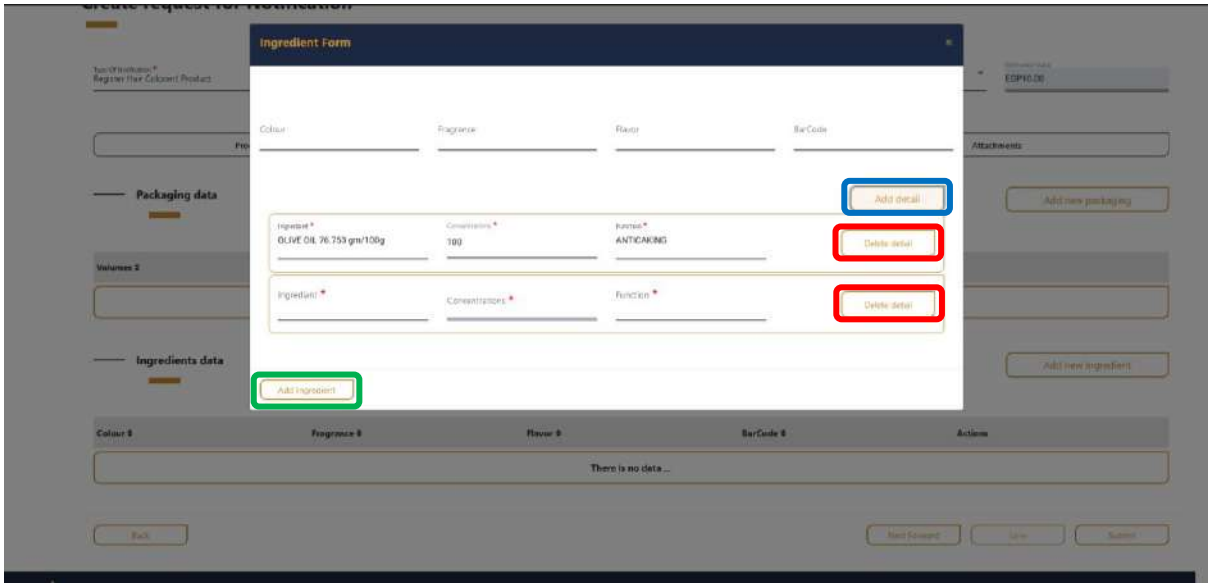
Click on add new add new packaging then a pop-up will appears including the form of packaging data Consists of



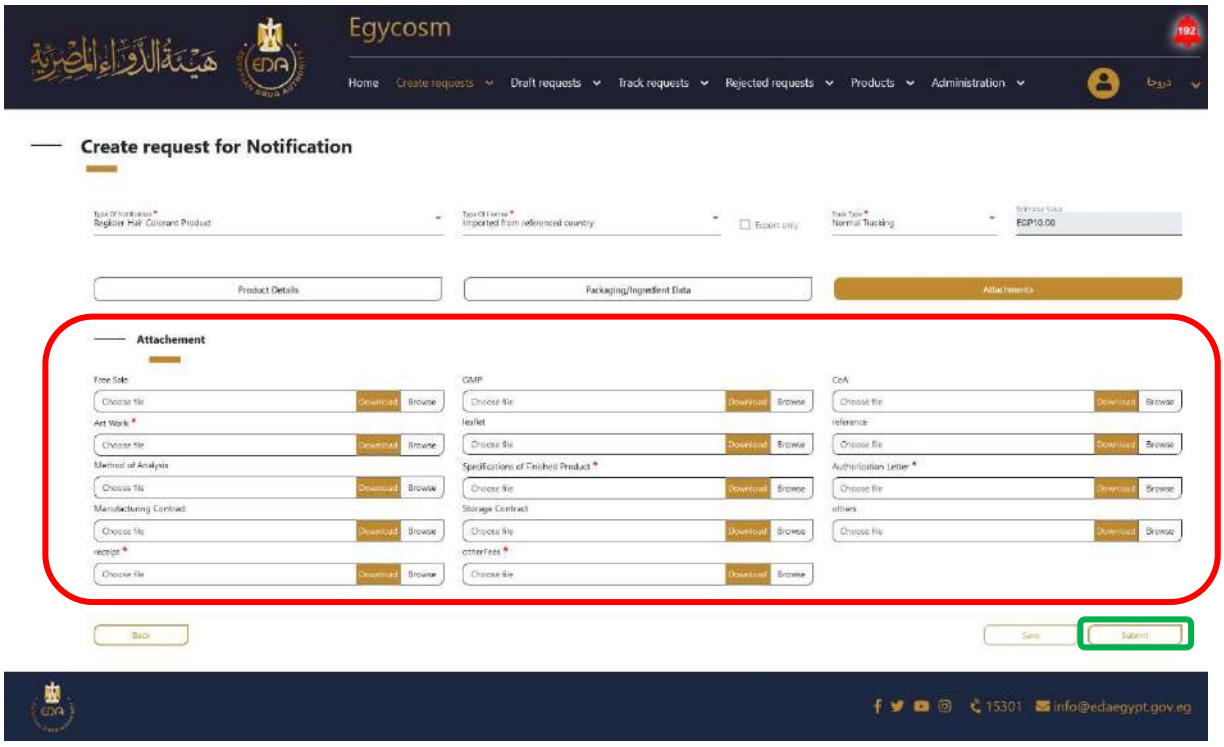
Click on add new add new Ingredient then a pop-up will appears including the form of details data Consists of



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

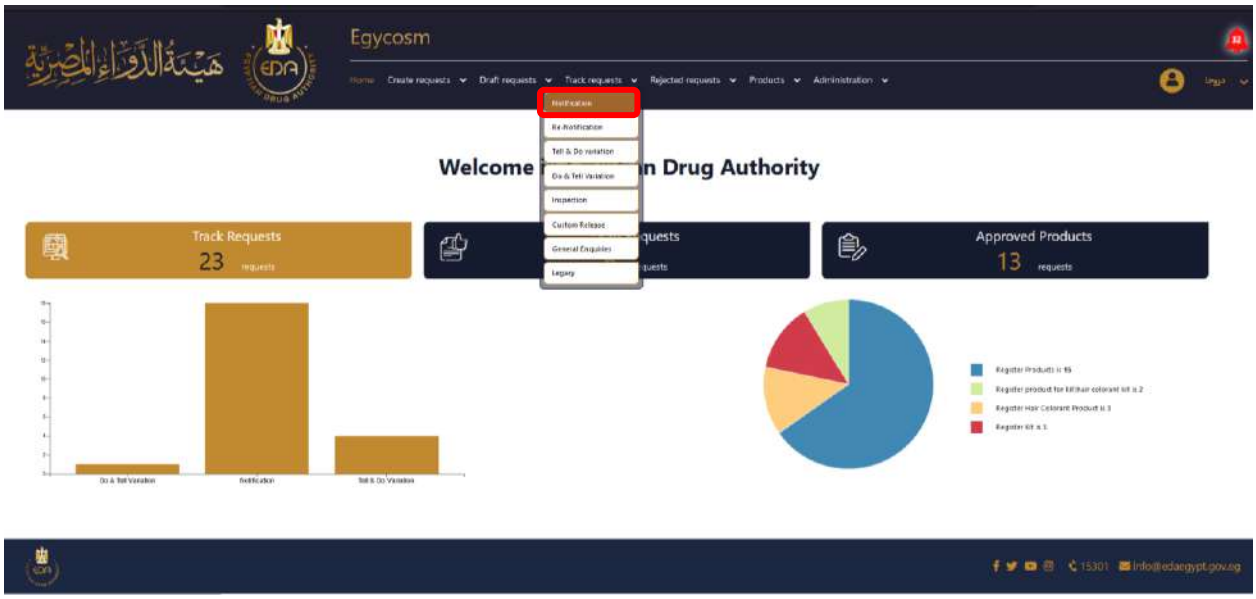


Here you add all the documents related to the product, each in the place designated for it in the tap of attachments (must be pdf)



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

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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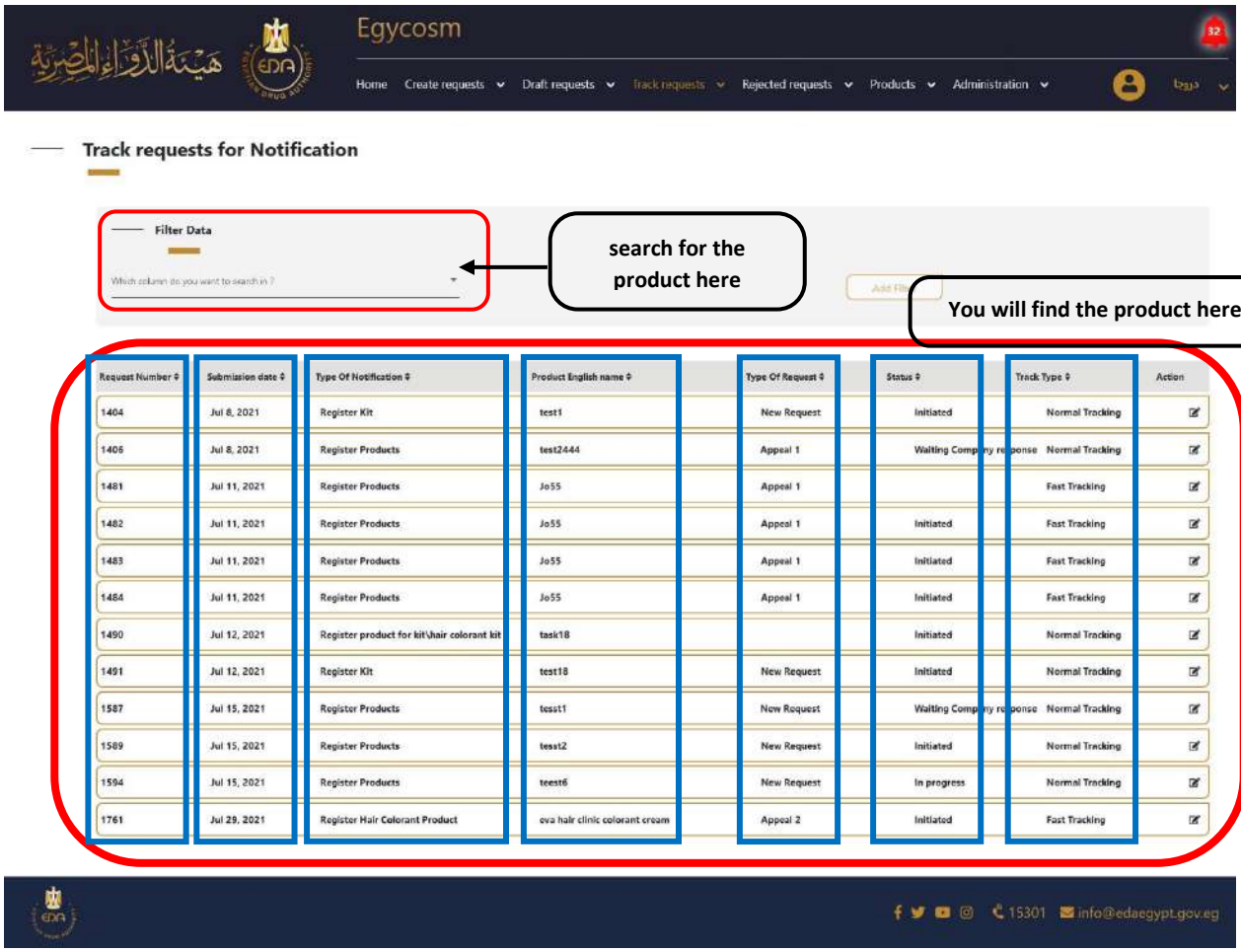
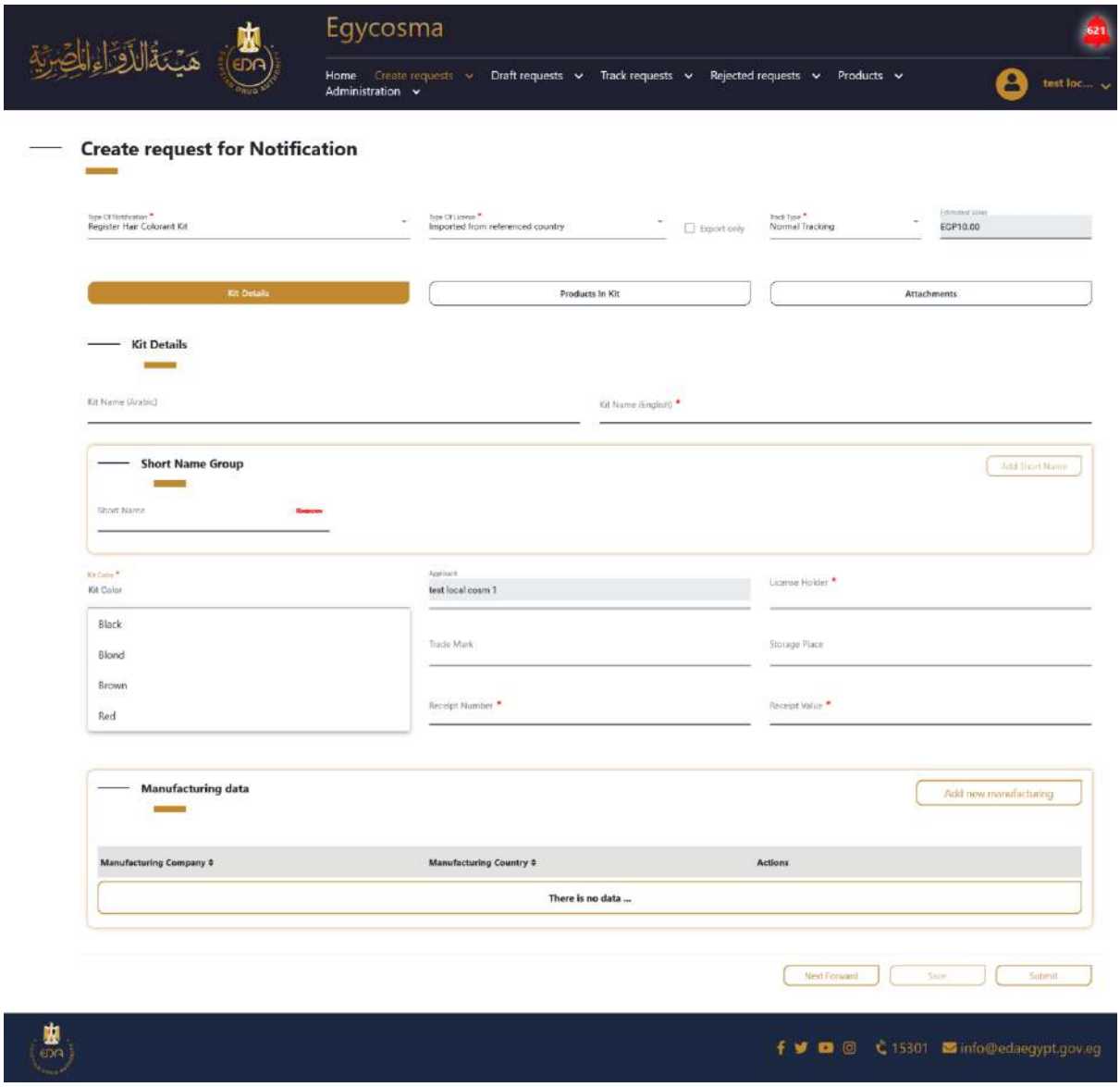


* In case the type of Notification is Register Hair Colorant KIT:

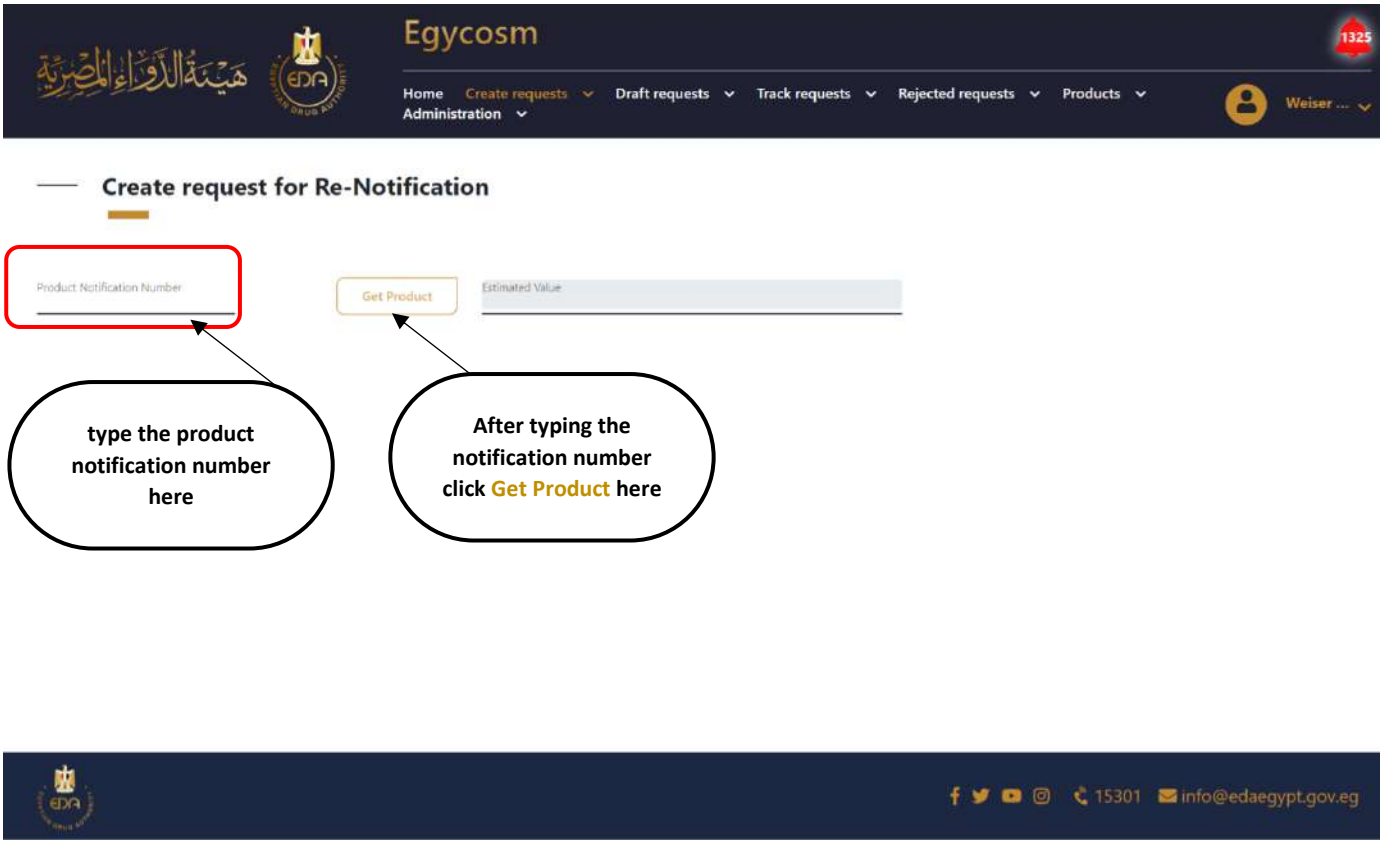
We find that the difference between Register kit and Register Hair Colorant KIT in the field of color kit … and Register Hair Colorant KIT can apply register product and register hair colorant product

- ❖ **Register Hair Colorant KIT Same steps of Register kit**

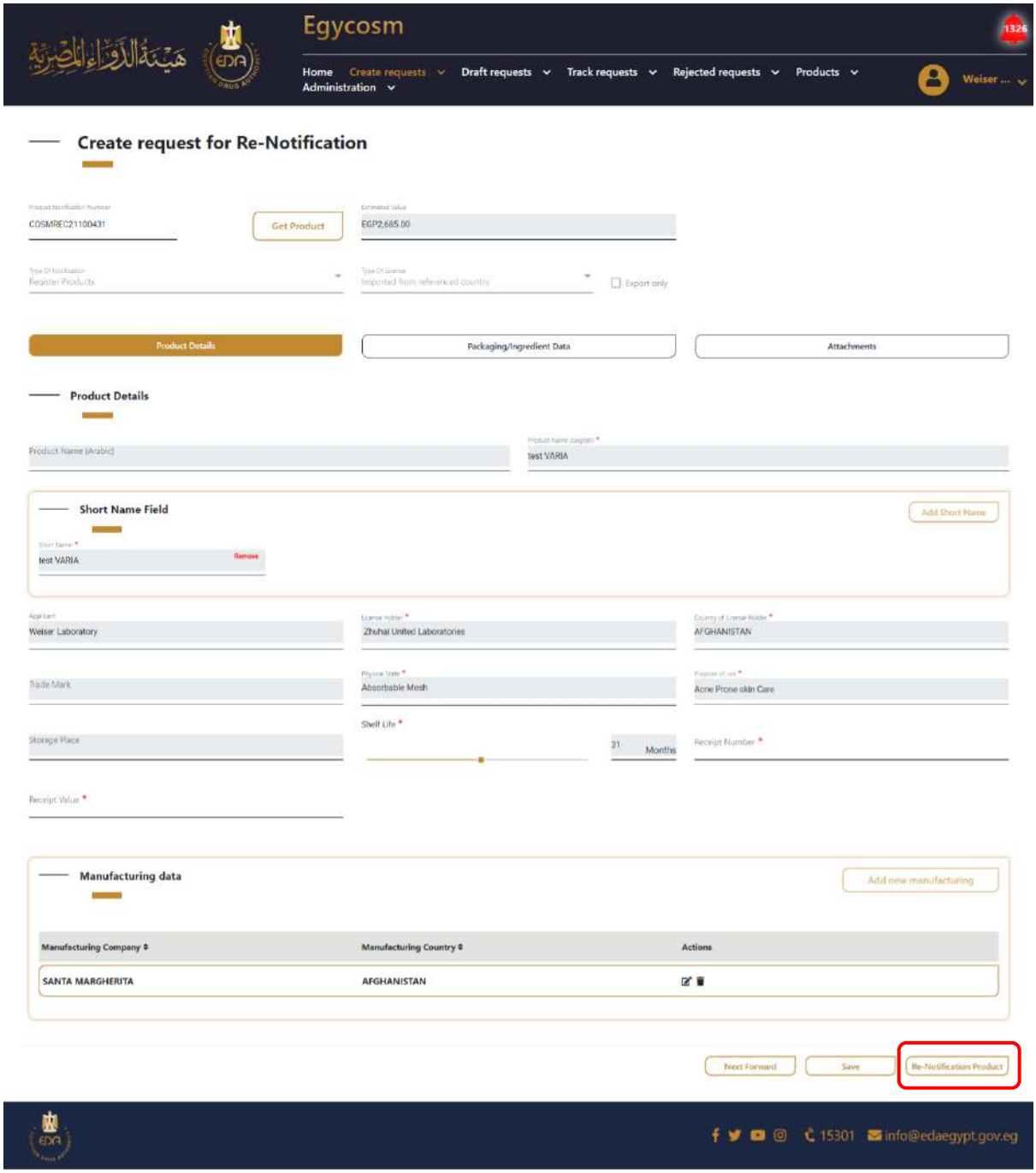


❖ Create requests for Re-Notification,

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

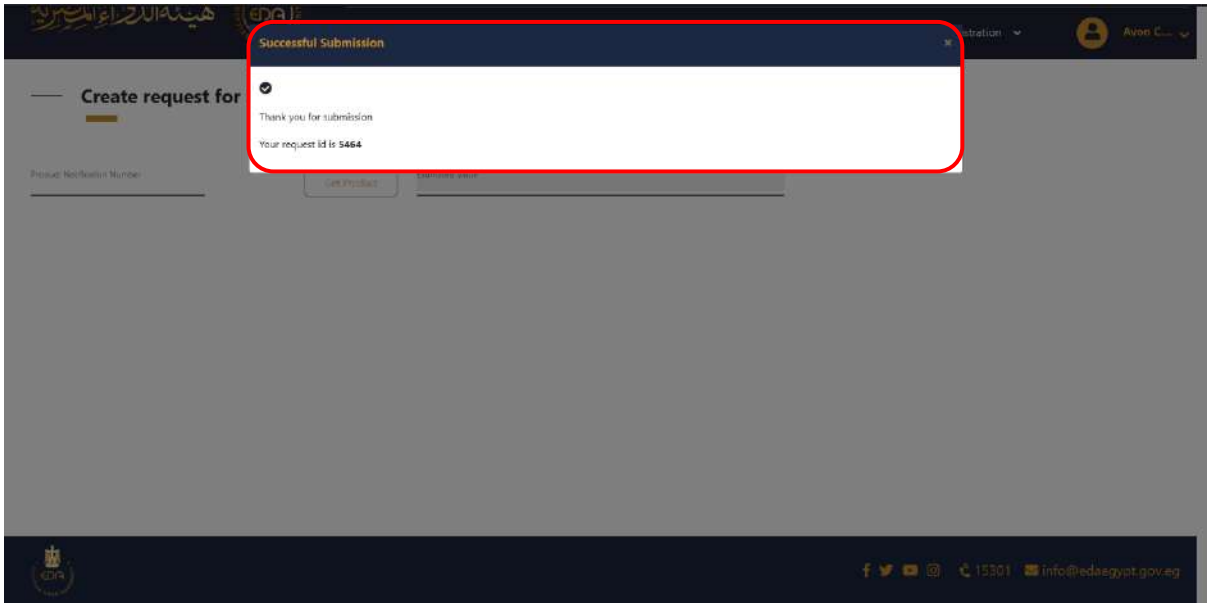


After clicking on Get Product icon, the screen will appear as in the below picture.



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.

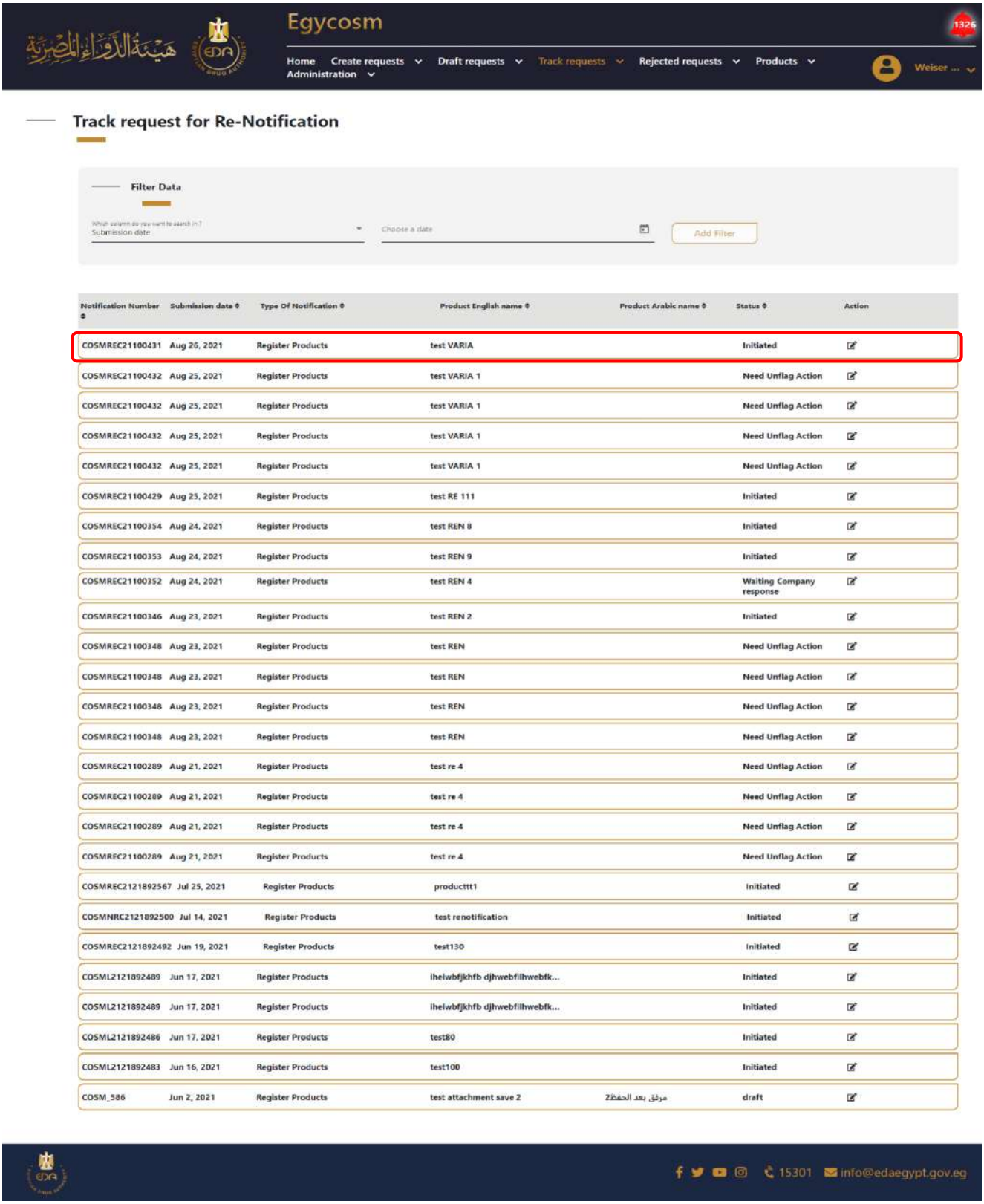
After clicking on Re-Notification Product, you will get a pop-up message as in the picture below.



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.

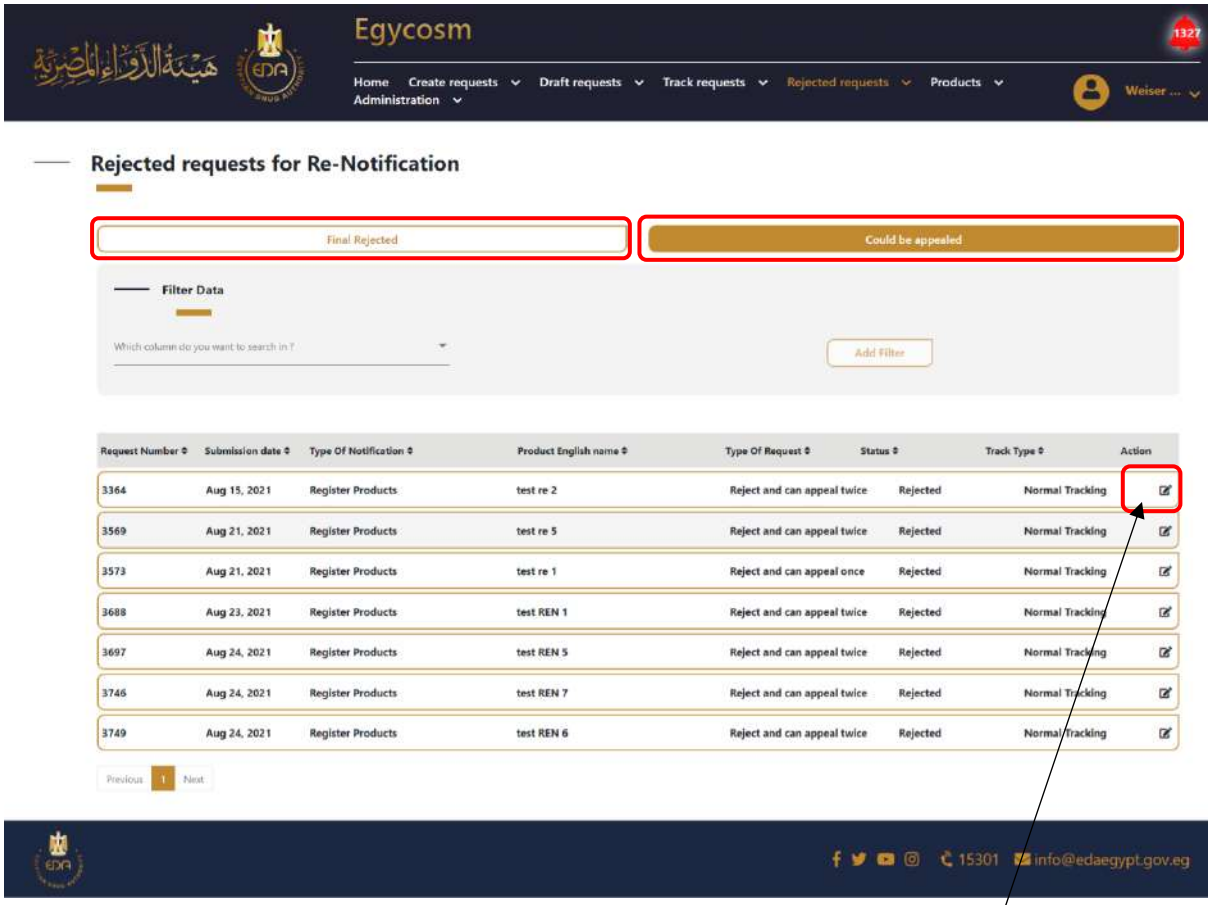
And here is your request appears at the top of the list as in the picture below.

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



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.**



By clicking on the action icon here, the page will be transferred to Create requests for Re-Notification, as appearing in the picture in the next page.

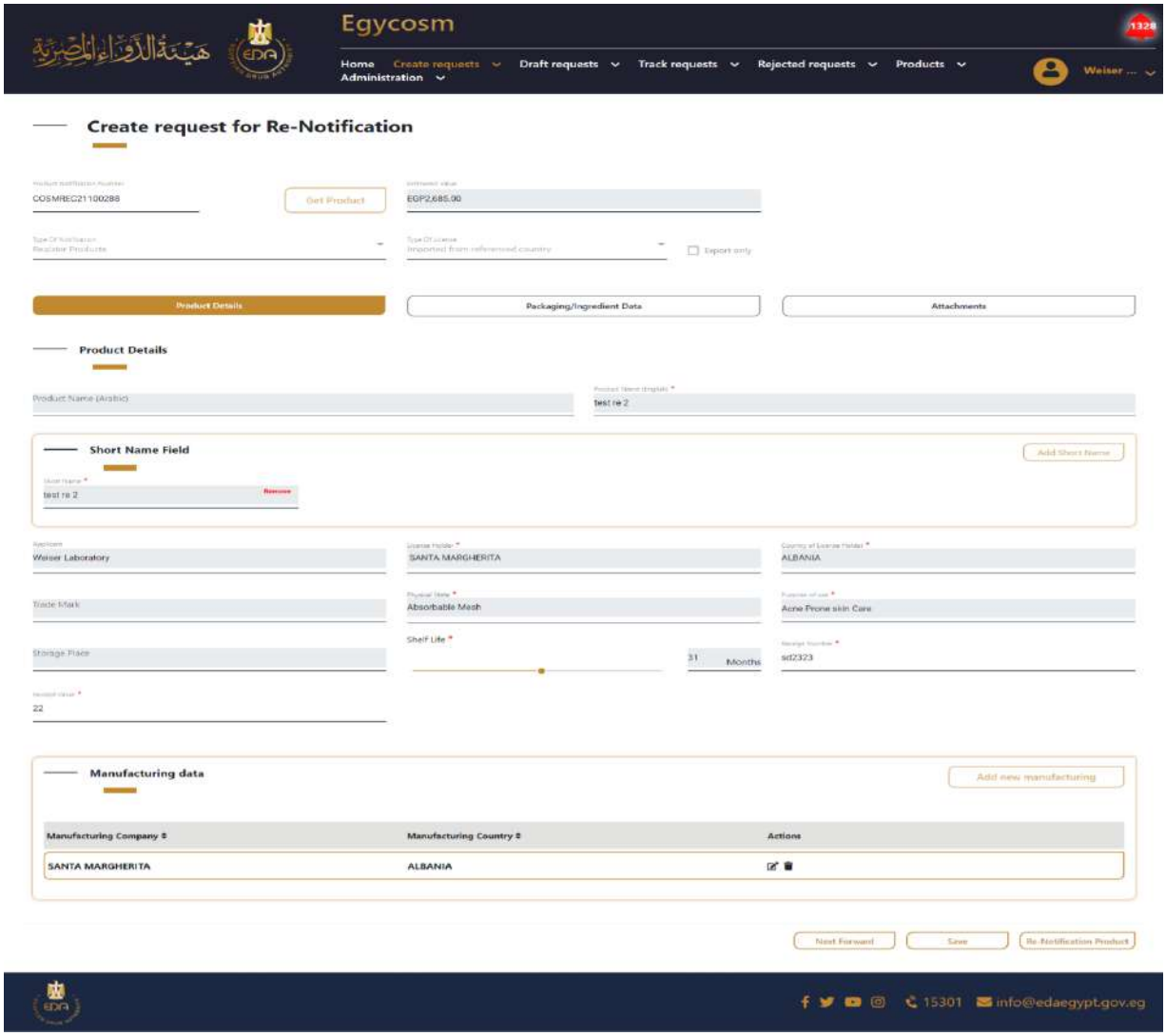
Request Number	Submission date	Type Of Notification	Product English name	Type Of Request	Status	Track Type	Action
5128	Sep 12, 2021	Register Products	test sH	Reject and can appeal once	Rejected	Normal Tracking	
5099	Sep 12, 2021	Register Products	test V1	Reject and can appeal twice	Rejected	Normal Tracking	
4878	Sep 7, 2021	Register Products	test reject reason 1	Reject and can appeal twice	Rejected	Normal Tracking	

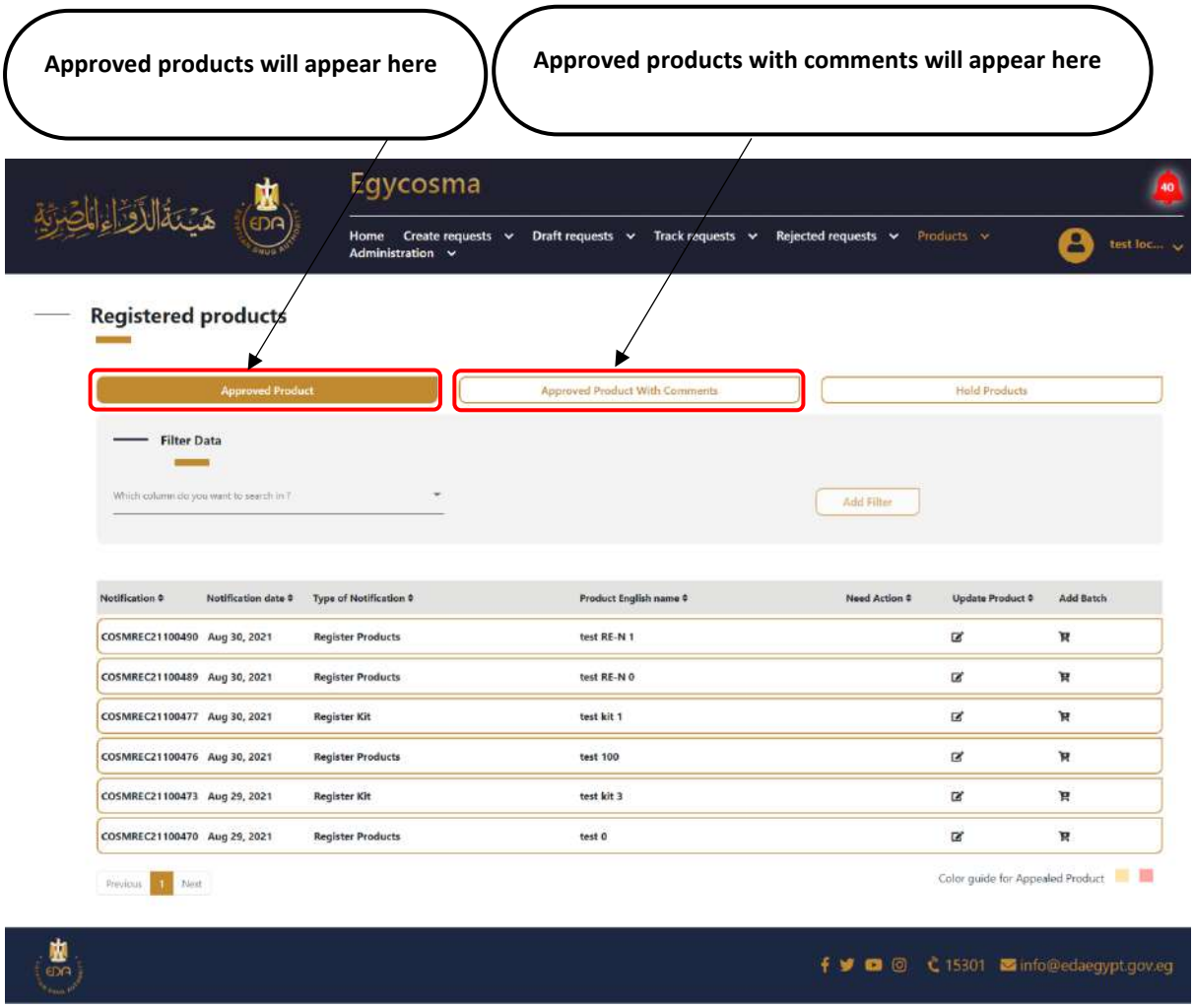
Request id : 4878
Submission date : Sep 7, 2021
Type Of Notification : Register Products
Product English name : test reject reason 1
Type Of Request : Reject and can appeal twice
Status : Rejected
Track Type : Normal Tracking
Reject Reasons :
1. تحتوي على بيانات غير مطابقة او غير صحيحة
2. منتهي الصلاحية

Request Number	Submission date	Type Of Notification	Product English name	Type Of Request	Status	Track Type	Action
4725	Sep 3, 2021	Register Products	test 555	Reject and can appeal twice	Rejected	Normal Tracking	
4705	Sep 2, 2021	Register Products	test	Reject and can appeal twice	Rejected	Normal Tracking	
4488	Sep 1, 2021	Register Products	TEST 88	Reject and can appeal once	Rejected	Normal Tracking	
4157	Aug 30, 2021	Register Products	test 756	Reject and can appeal twice	Rejected	Normal Tracking	

Previous 1 2 Next

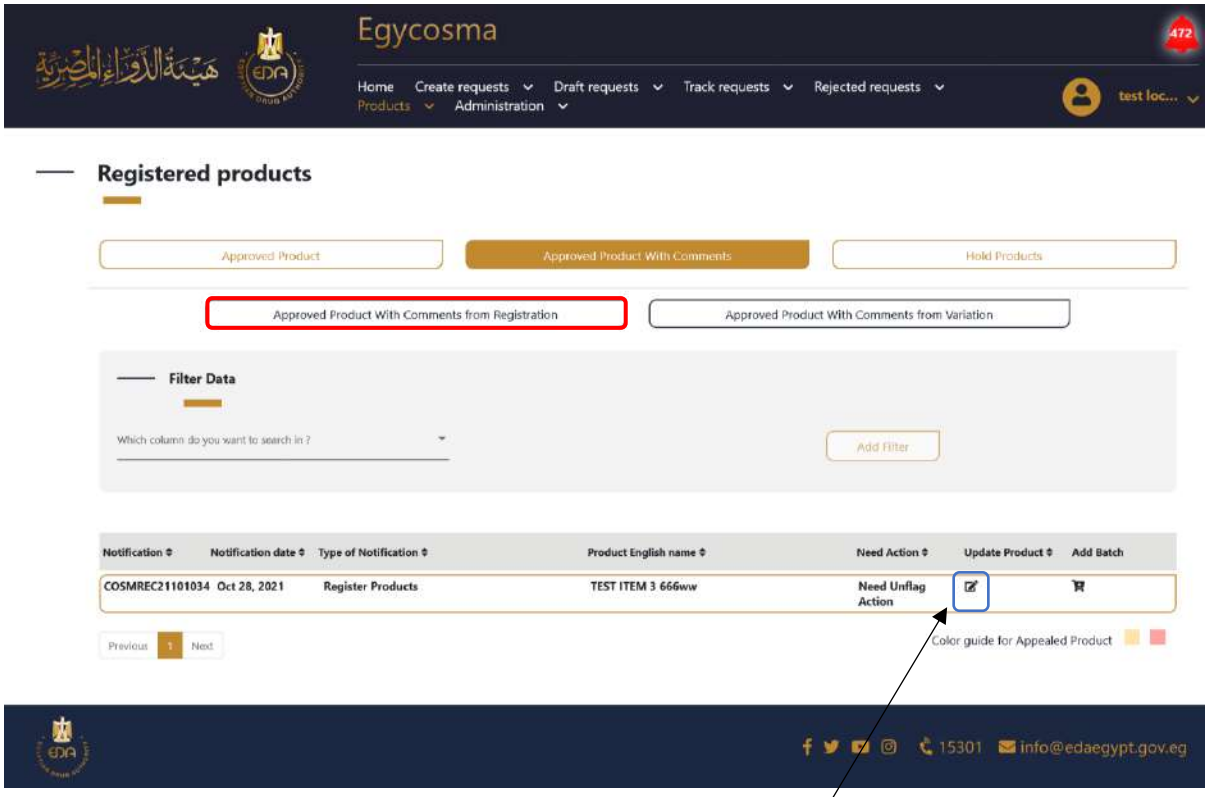
If you click on any product, you can see the reject reason here




Approved products will appear here
Approved products with comments will appear here
Egycosma
Home
Create requests
Draft requests
Track requests
Rejected requests
Products
Administration
test loc...
Registered products
Approved Product
Approved Product With Comments
Hold Products
Filter Data
Which column do you want to search in ?
Add Filter
Notification
Notification date
Type of Notification
Product English name
Need Action
Update Product
Add Batch
COSMREC21100490 Aug 30, 2021 Register Products test RE-N 1
COSMREC21100489 Aug 30, 2021 Register Products test RE-N 0
COSMREC21100477 Aug 30, 2021 Register Kit test kit 1
COSMREC21100476 Aug 30, 2021 Register Products test 100
COSMREC21100473 Aug 29, 2021 Register Kit test kit 3
COSMREC21100470 Aug 29, 2021 Register Products test 0
Previous
1
Next
Color guide for Appealed Product
15301
info@edaegypt.gov.eg

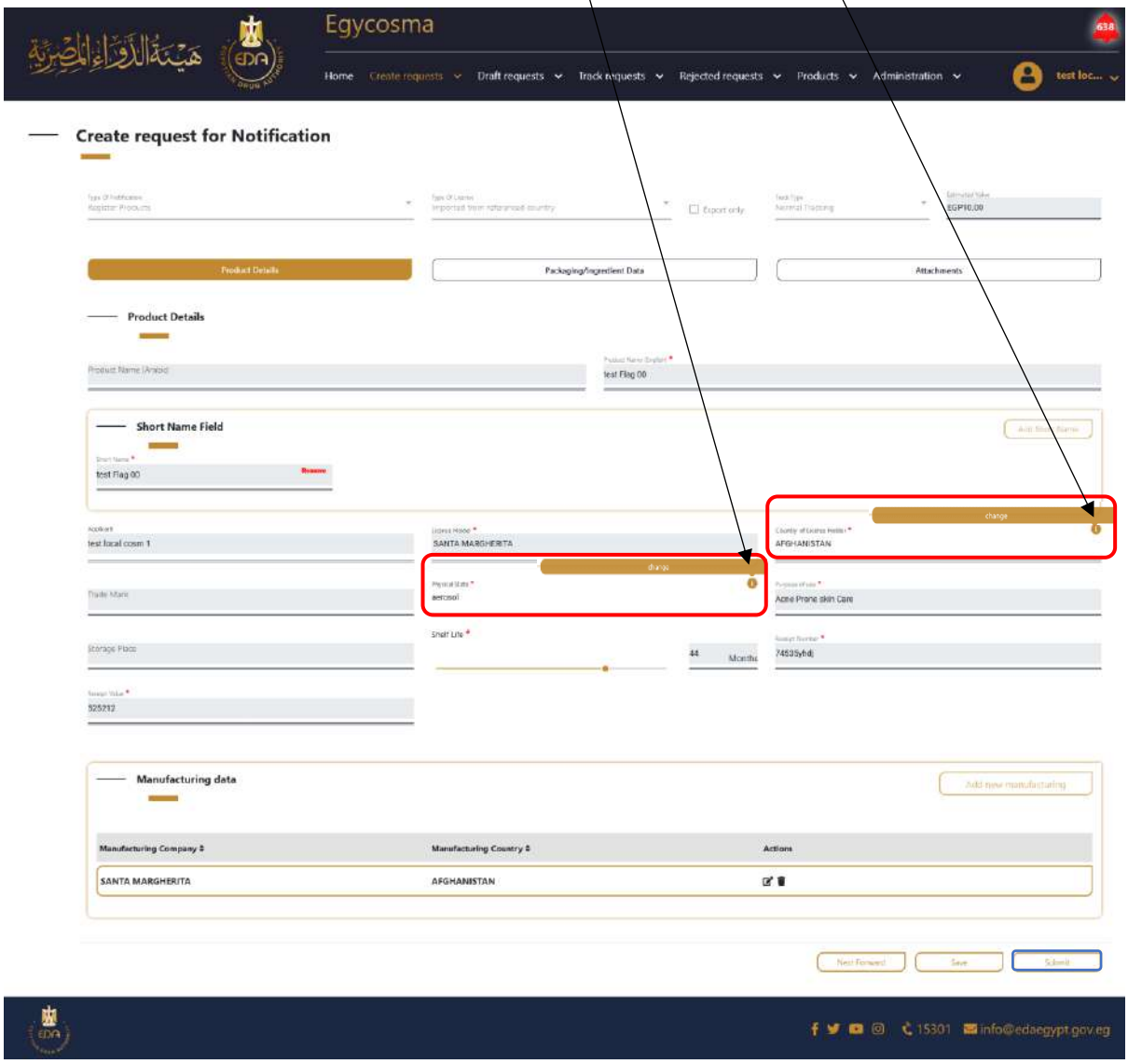
Approved products with comments from registration (FLAG) as in the below picture. and these products need (UNFLAG) action

- ❖ **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**



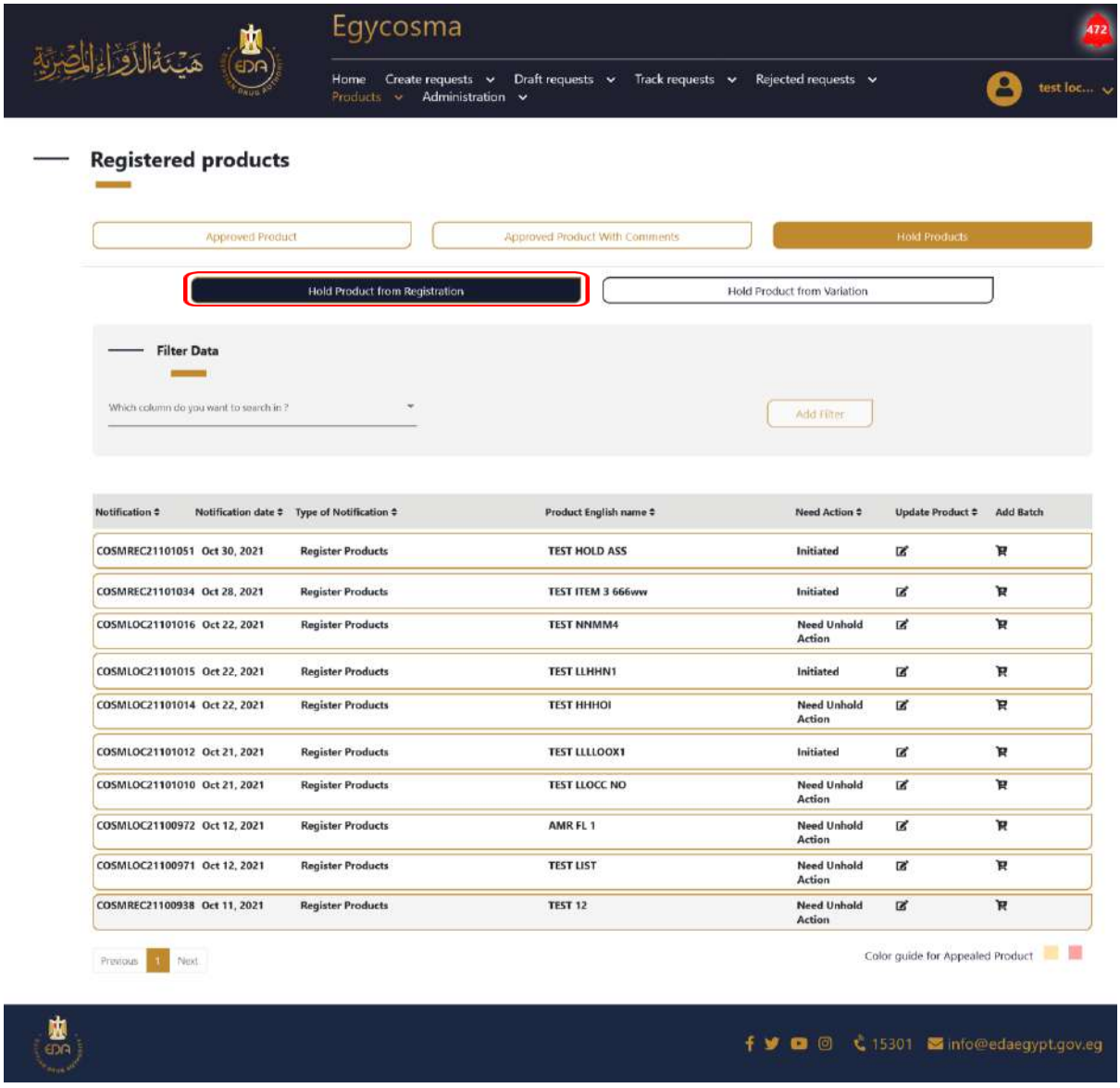
First step click on the action icon here, the page will be transferred to unflag product, as appearing in the picture in the next page.

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

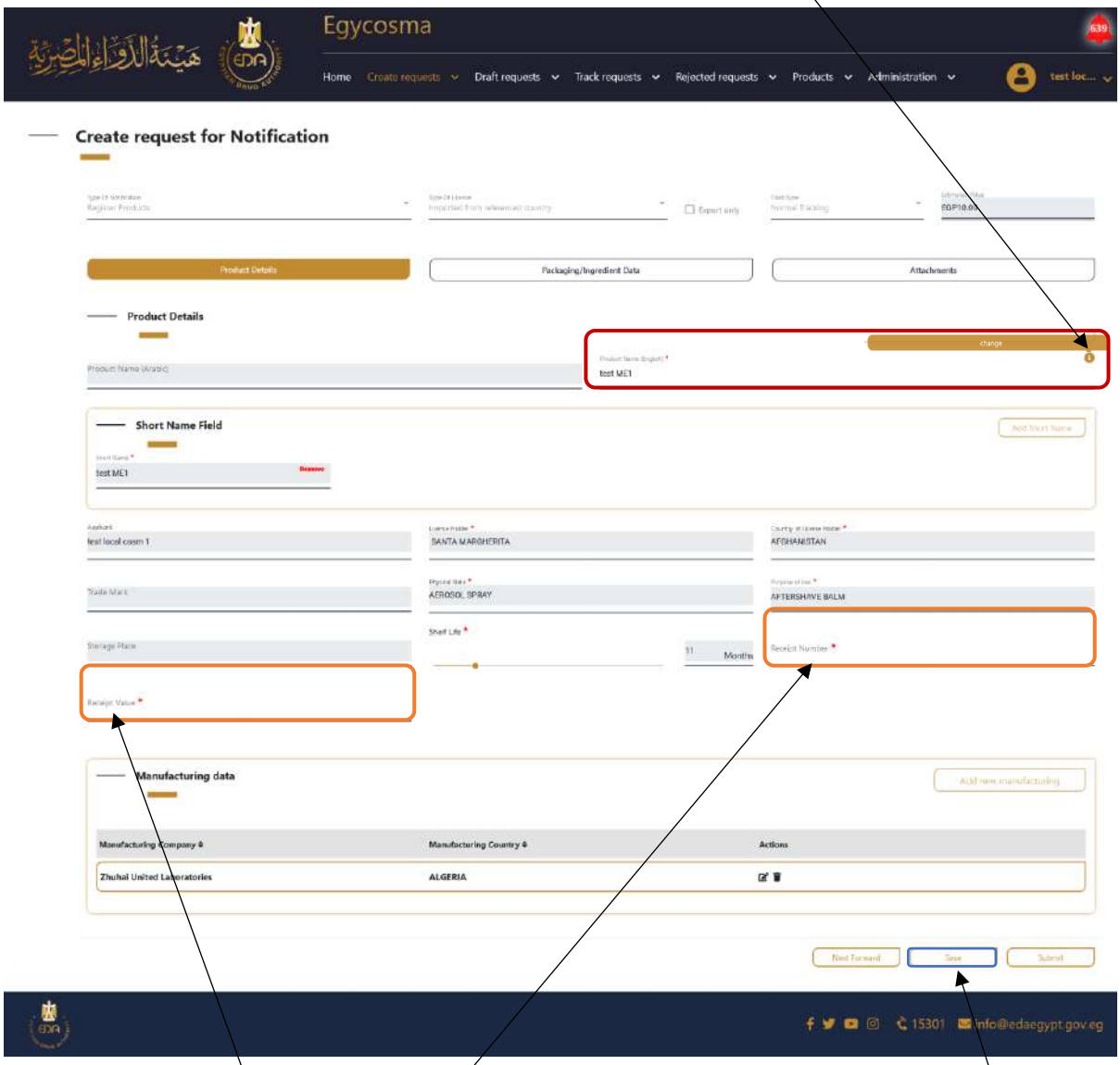


Hold products from registration as in the below picture , and these products need (UNHOLD) action.

- ❖ **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**



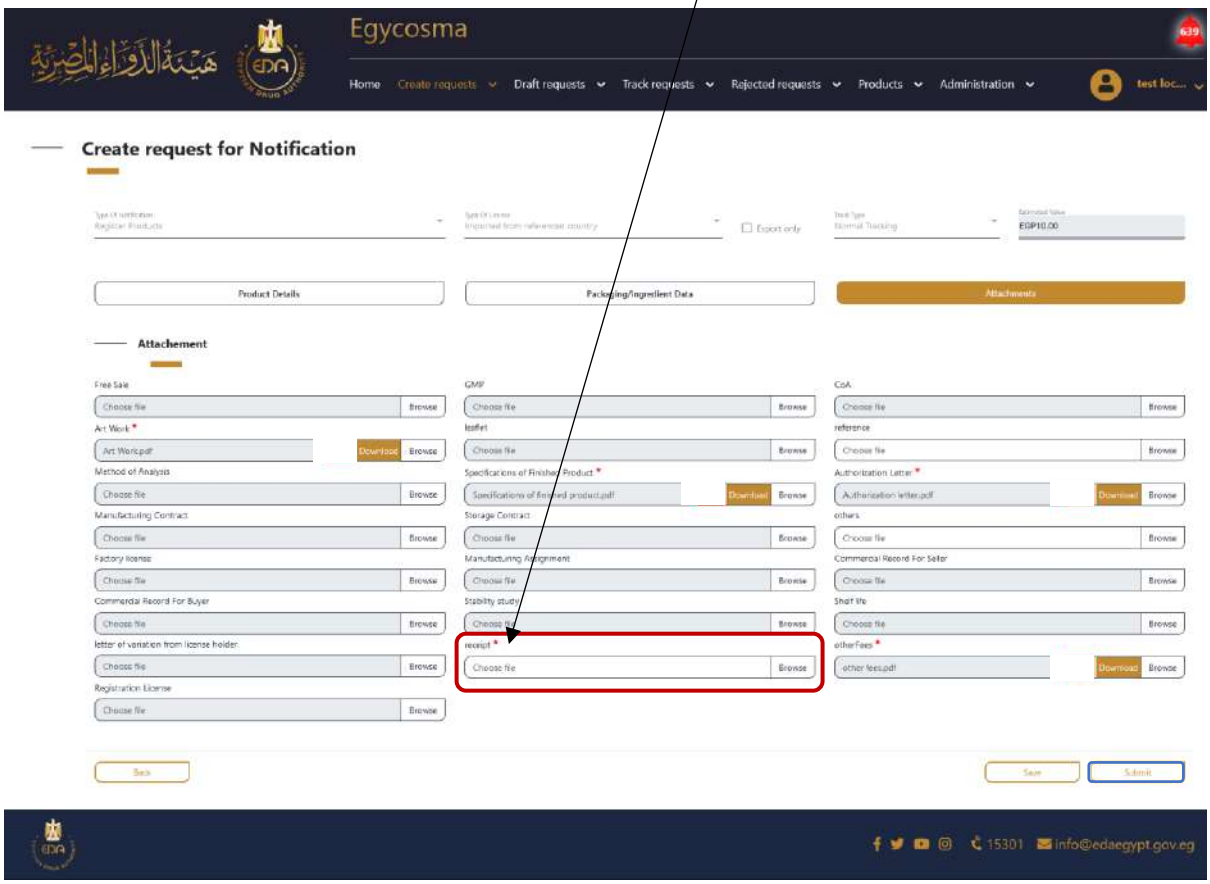
In this step you need to **check all comments**



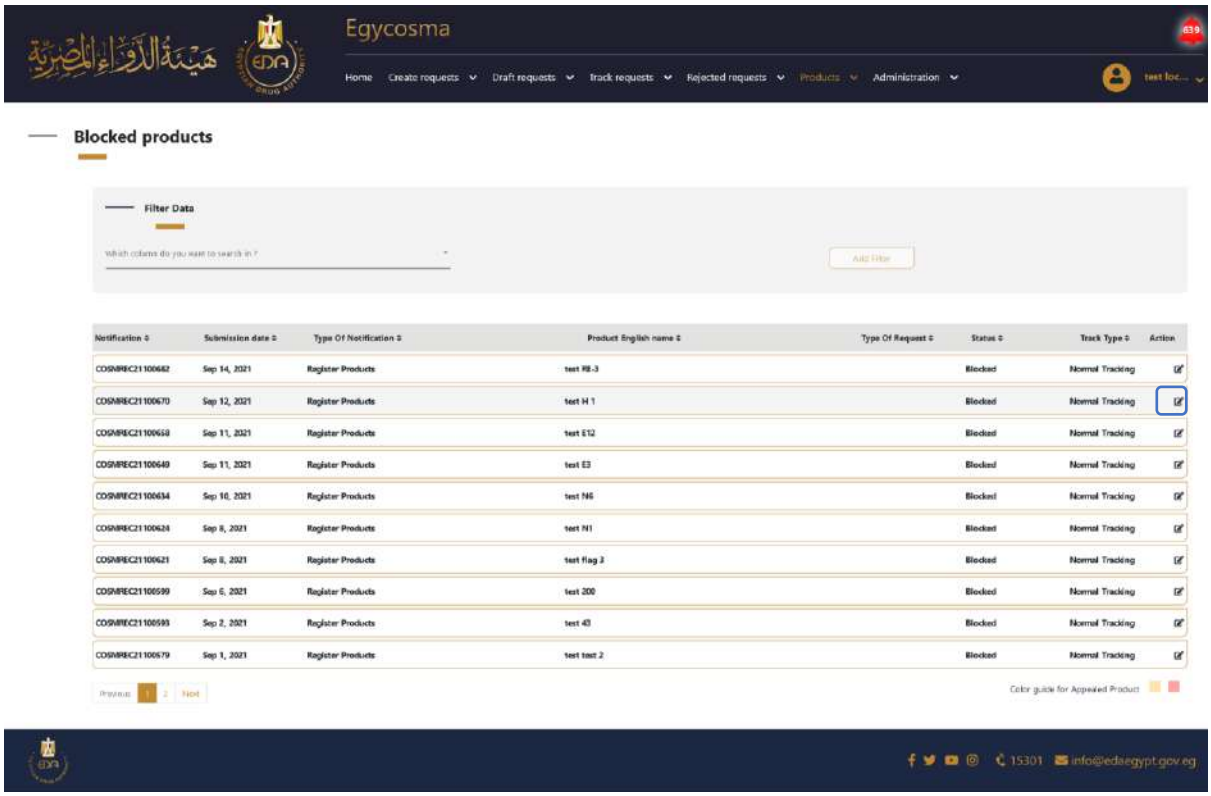
you have to enter receipt number, and receipt value

You need to save first to enable add receipt attachment

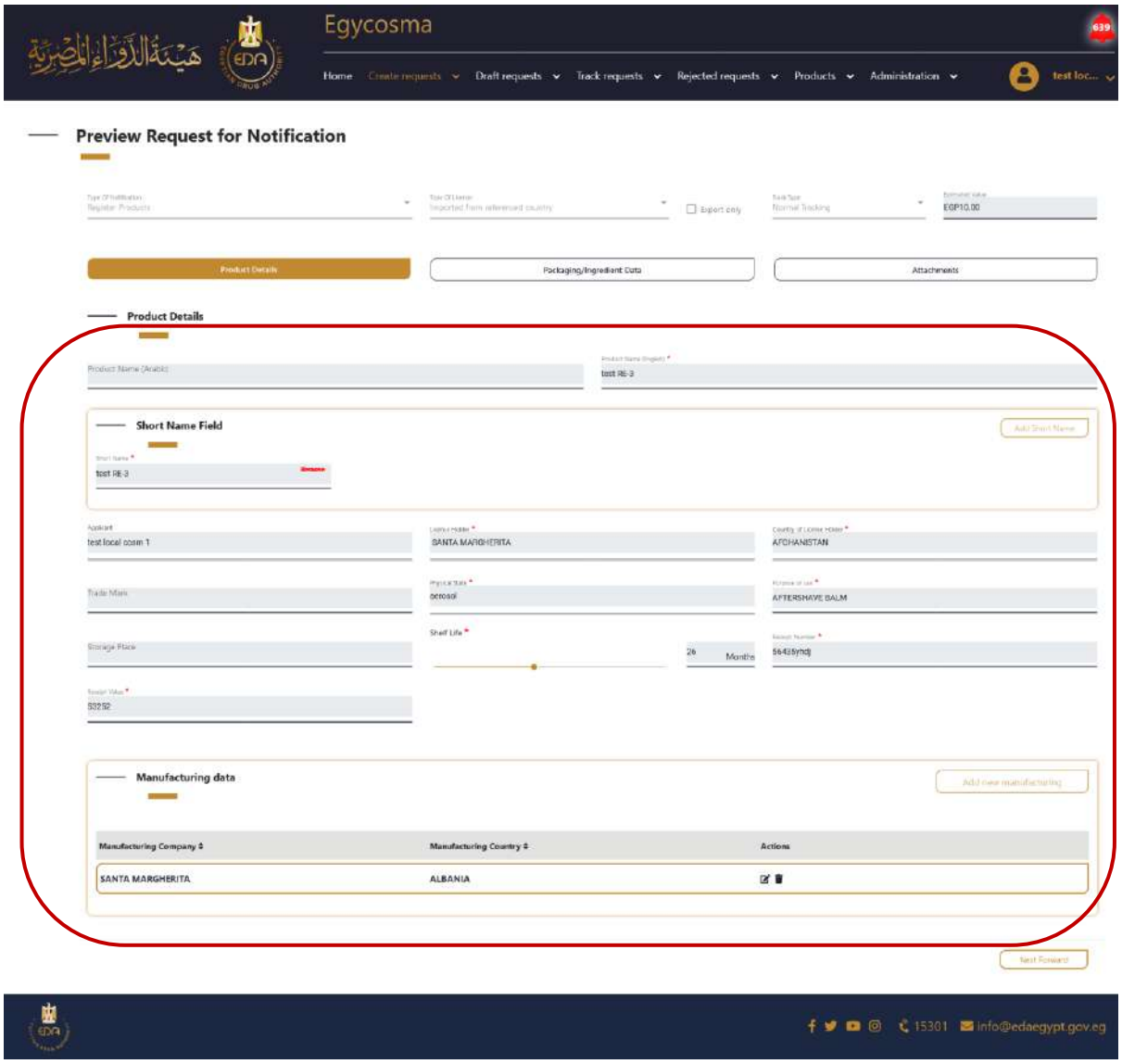
You need to add receipt attachment once you complete this step you can click submit



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**.



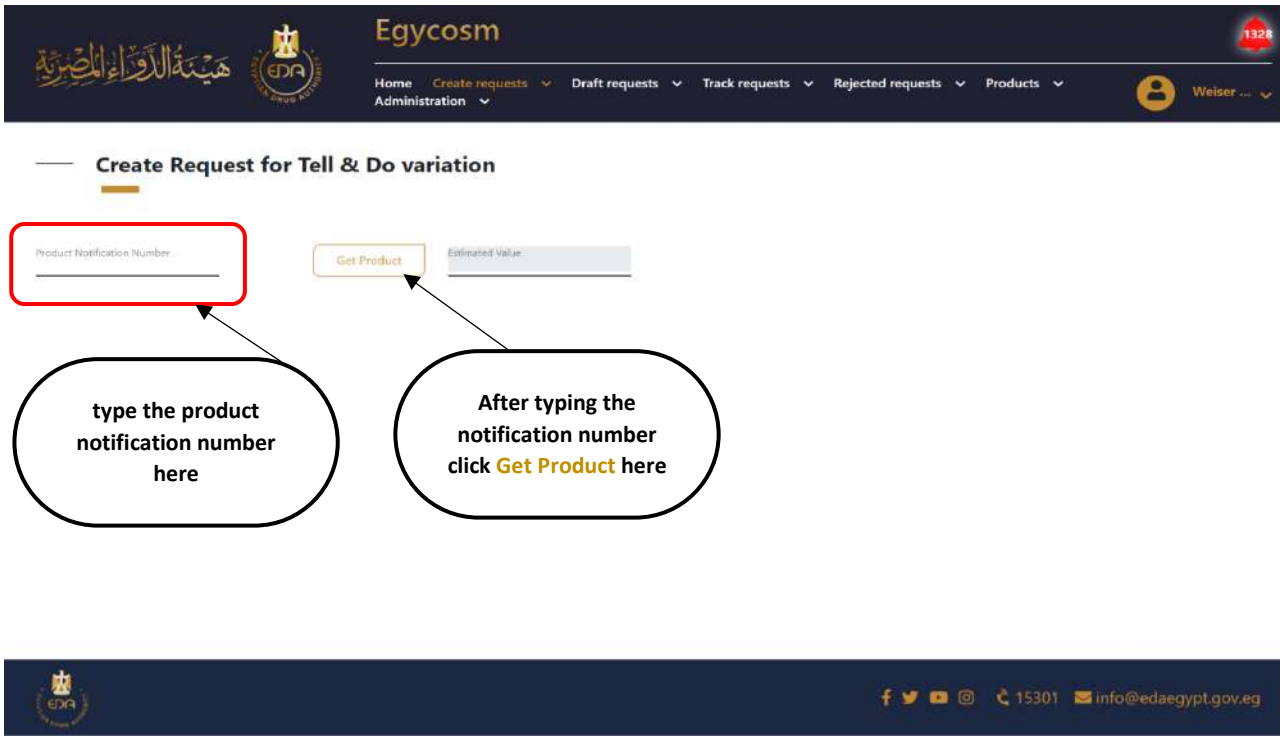
Product read only in blocked product
You cannot take any action



❖ Create request for Tell & Do Variation,

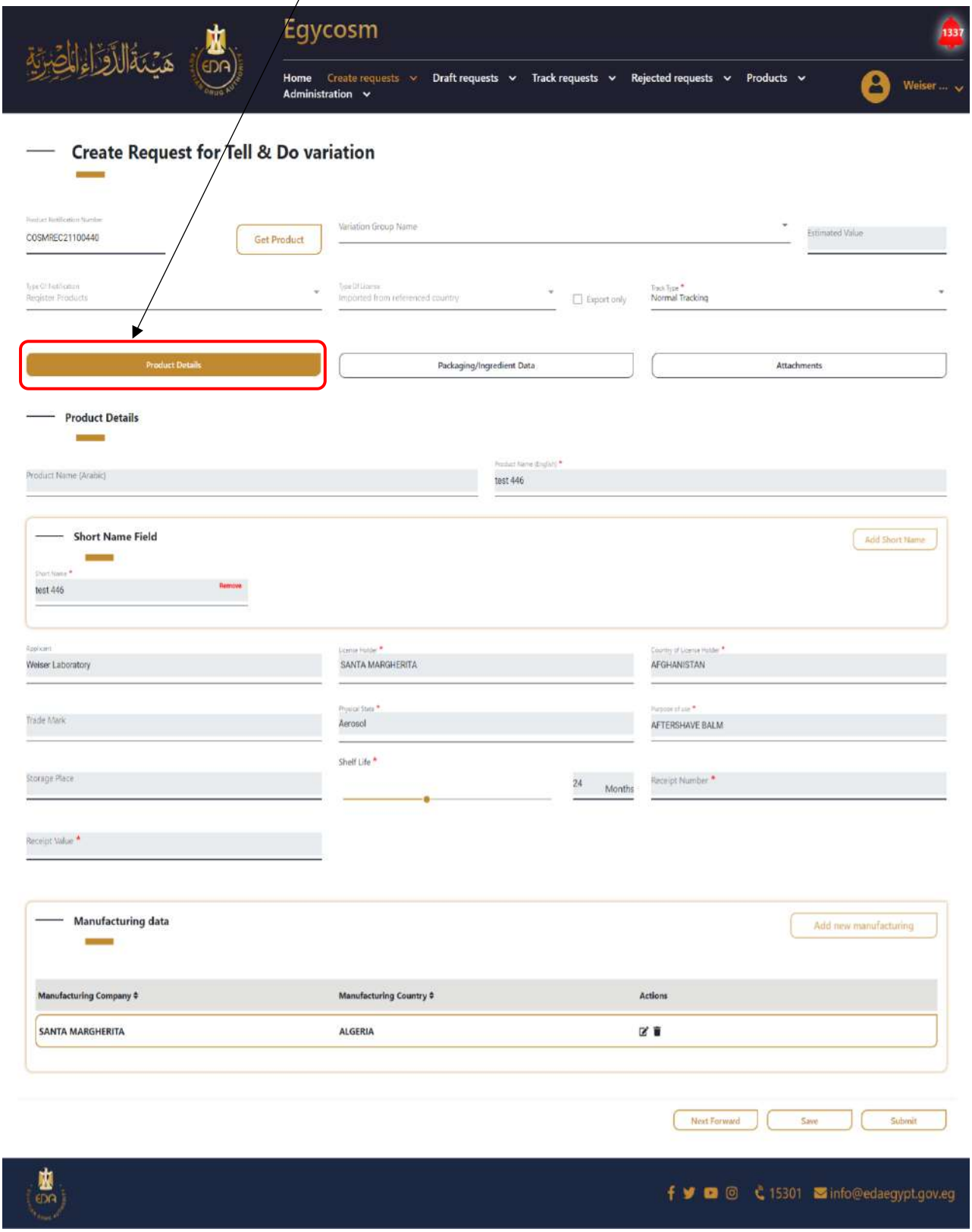
And here if you want to make some changes on a product:

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

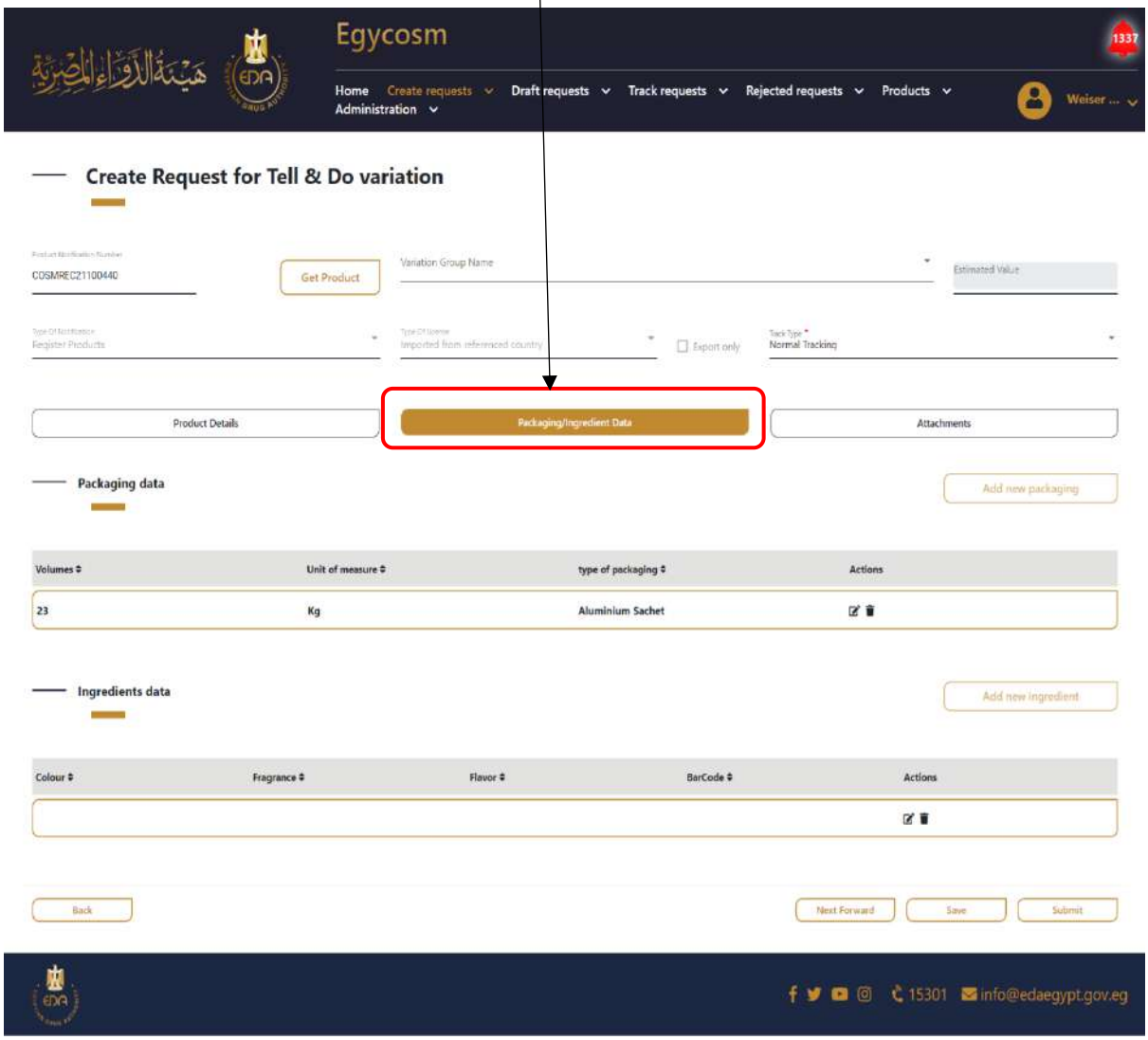


After typing the product notification number, and click Get product, the screen will be as is in the picture in the next page.

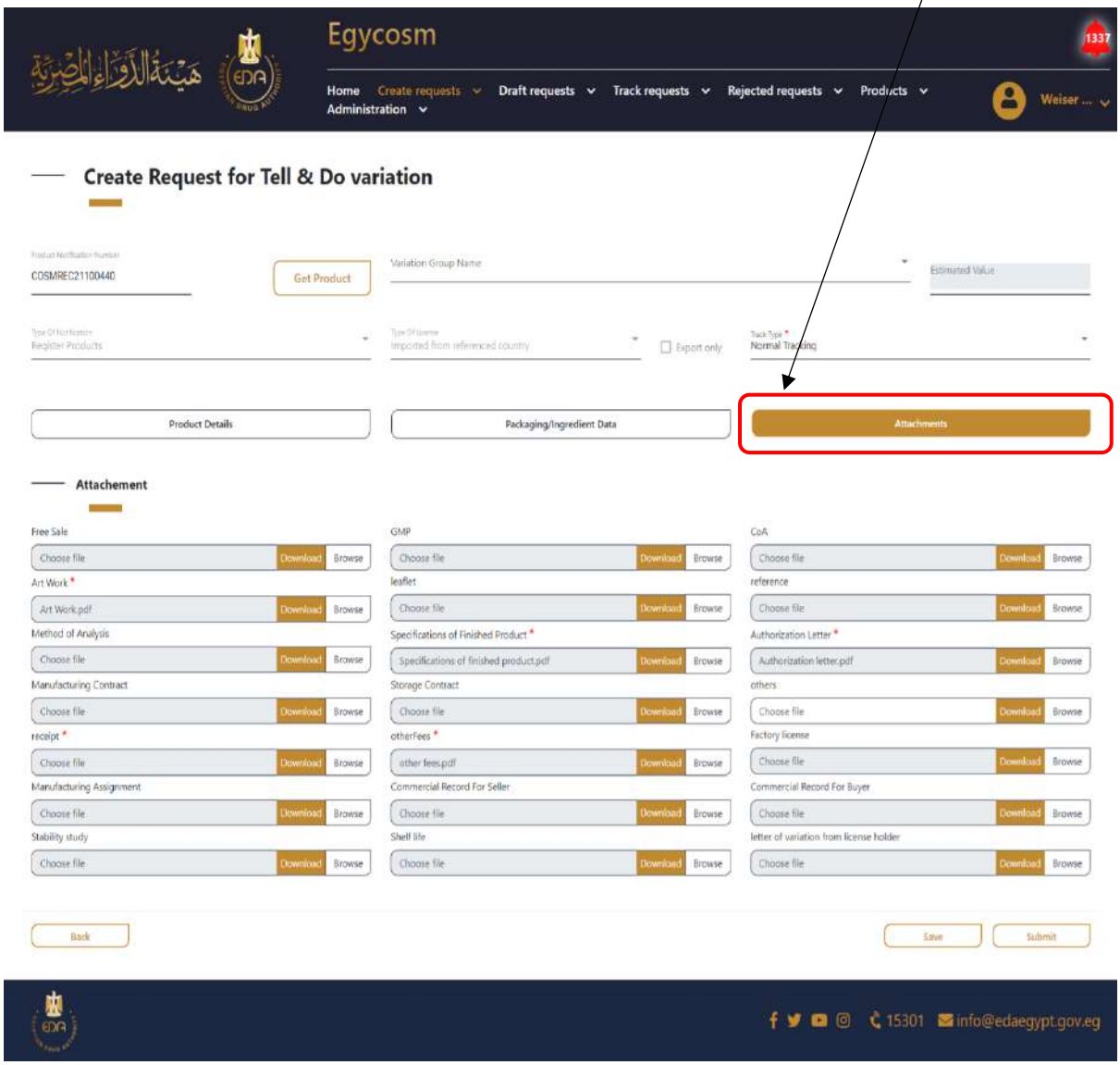
Here is the page of Product details

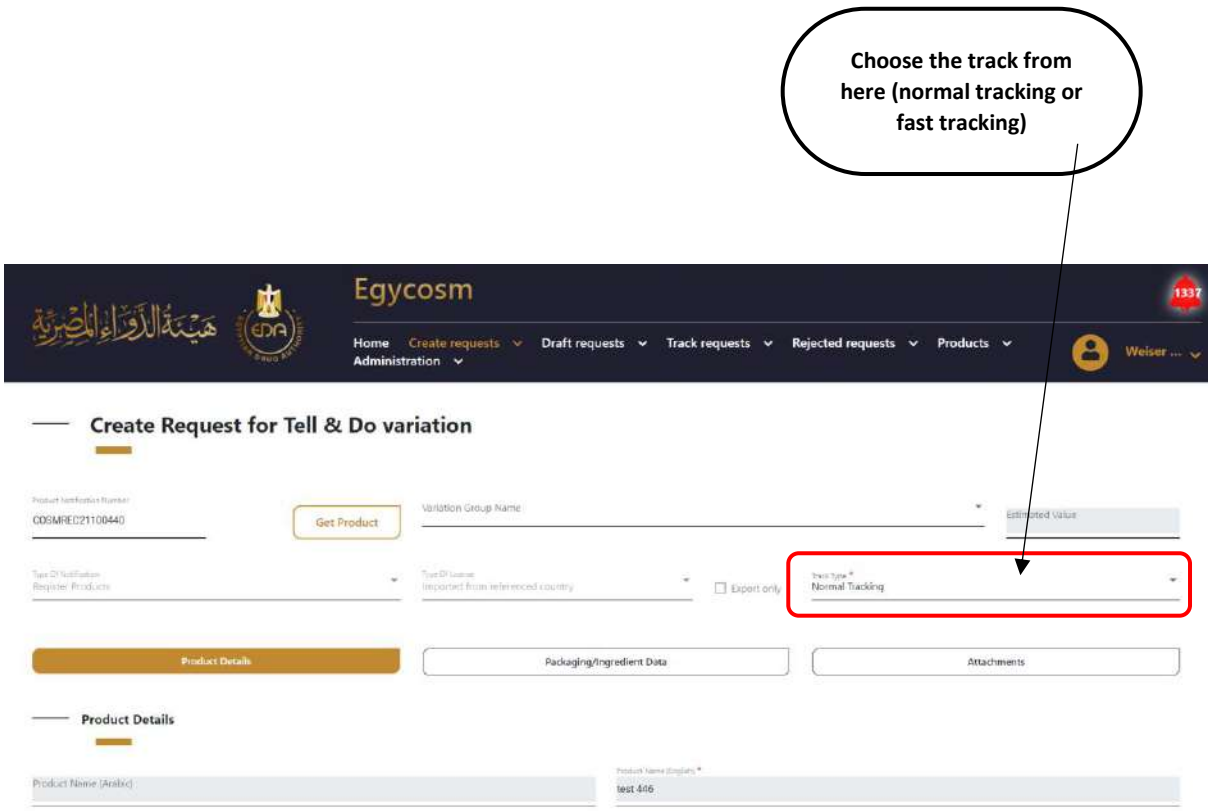


Here is the page of Packaging/Ingredients Data

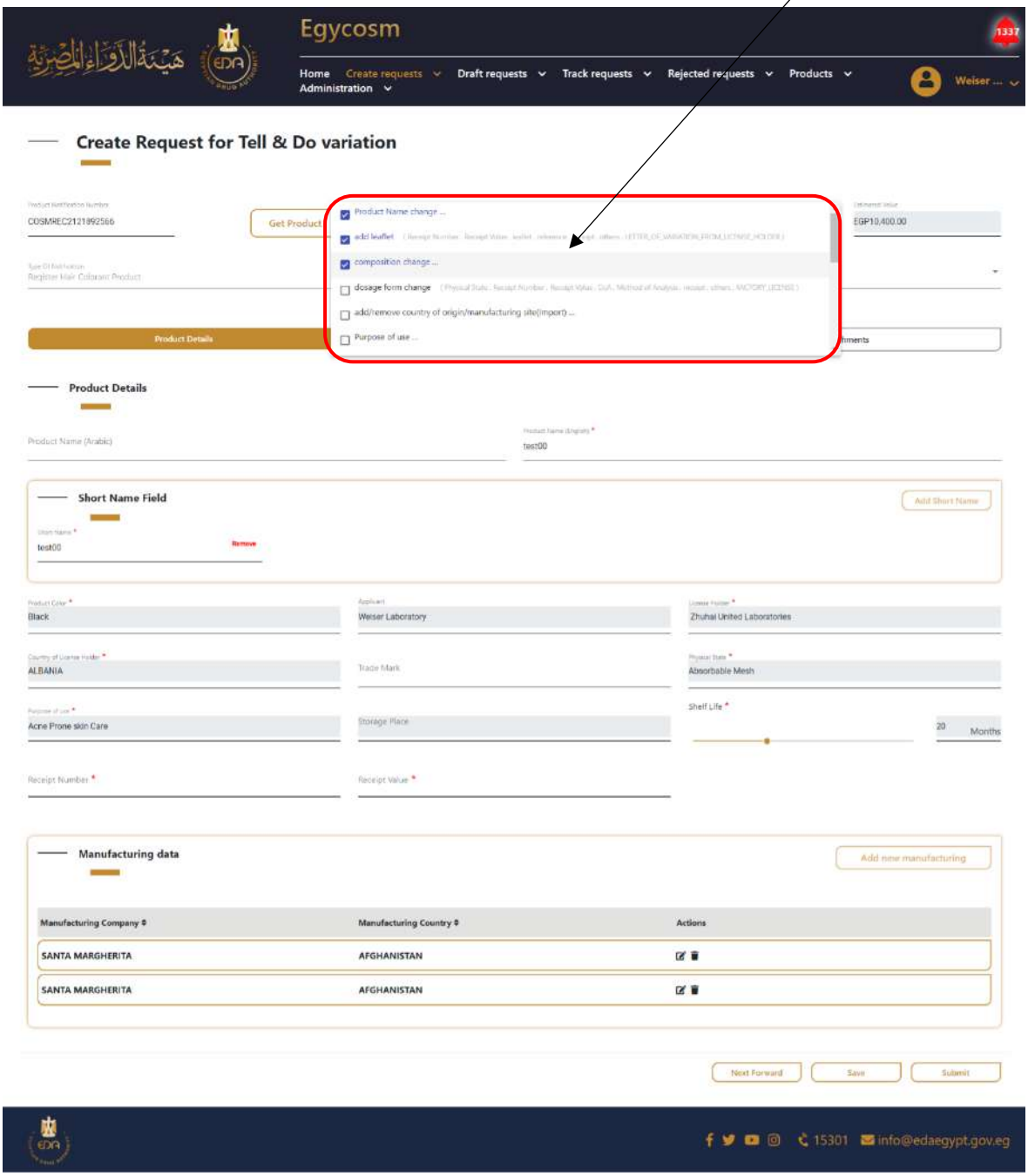


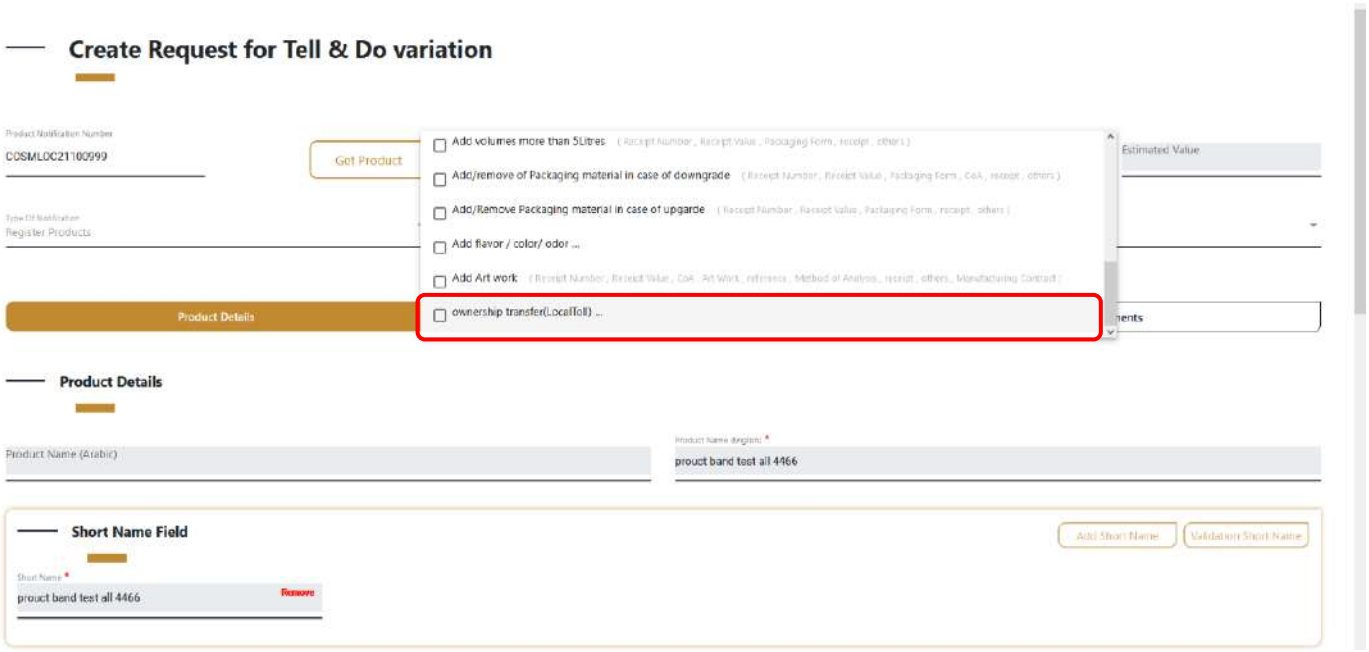
Here is the page of attachment (must be pdf)




Choose the track from here (normal tracking or fast tracking)
Egycosm
Home
Create requests
Draft requests
Track requests
Rejected requests
Products
Administration
Weiser ...
Create Request for Tell & Do variation
COSMREC21100440
Get Product
Variation Group Name
Estimated Value
Export only
Normal Tracking
Product Details
Packaging/Ingredient Data
Attachments
Product Details
Product Name (Arabic)
test 446

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

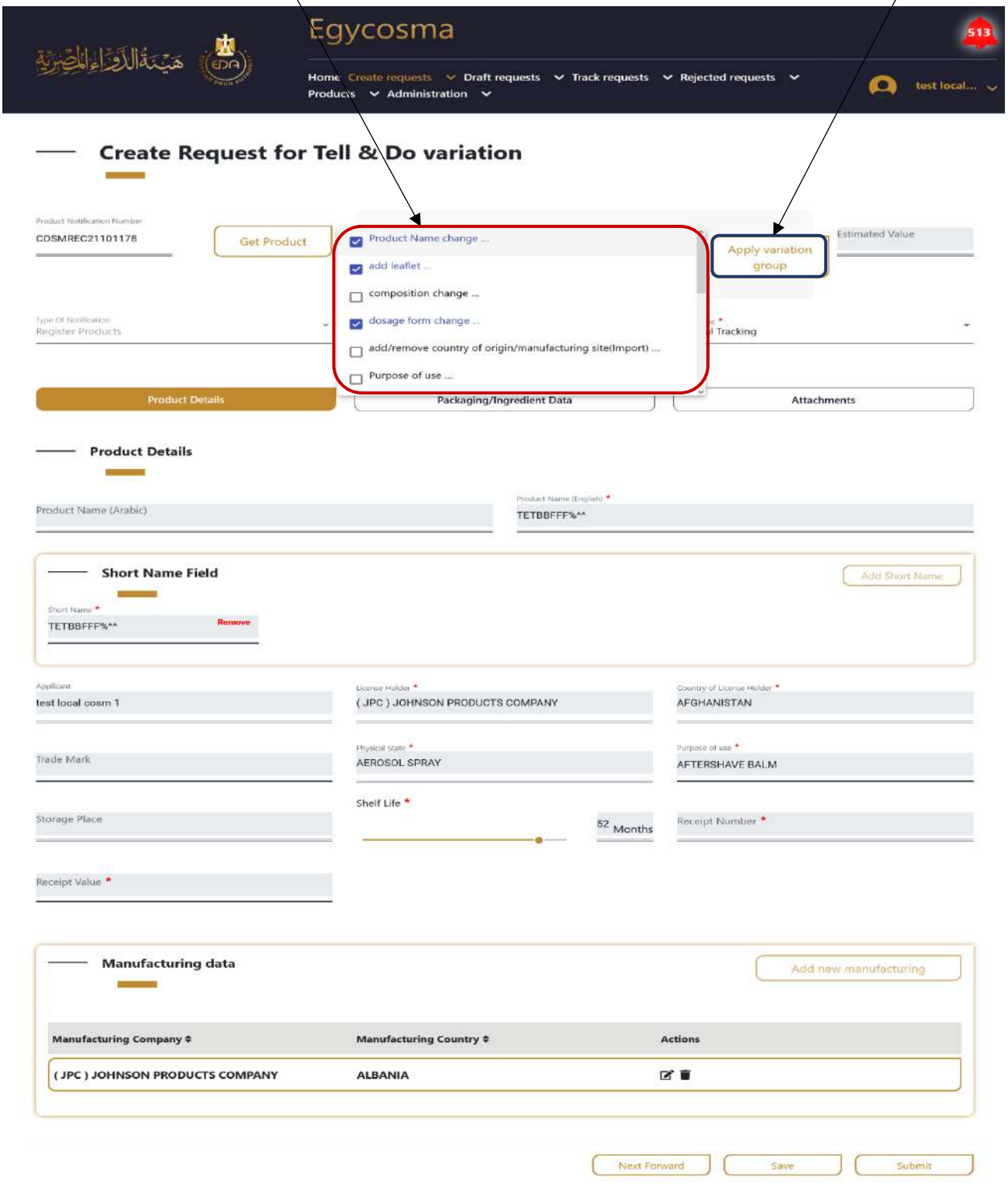




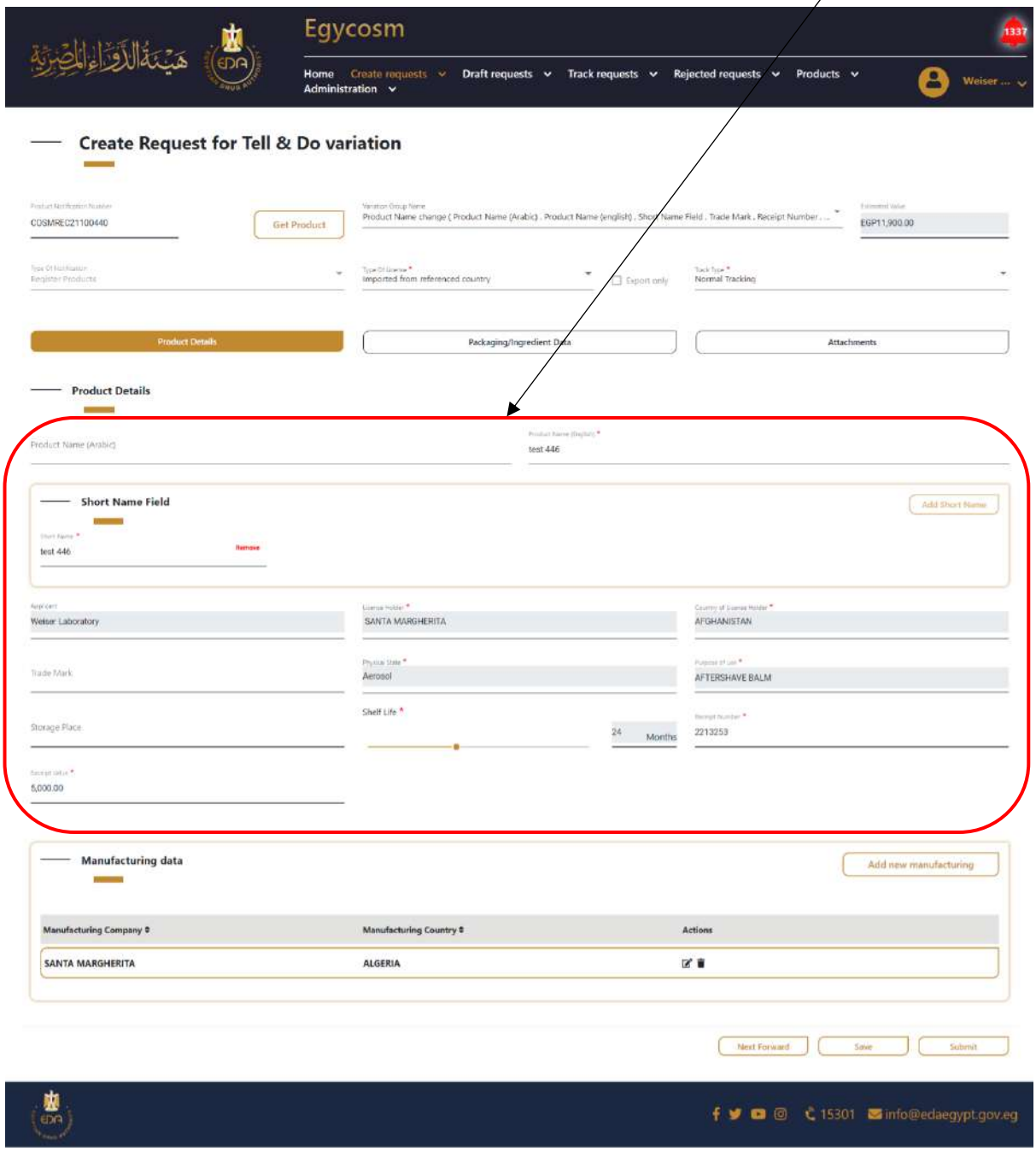
- **If company need to choose a type of variation** (ownership transfer)
- **Please go to the admin of variation in the authority and follow the procedures for that process .**

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.

when you choose group of variation you need to click apply variation group to open fields of this groups

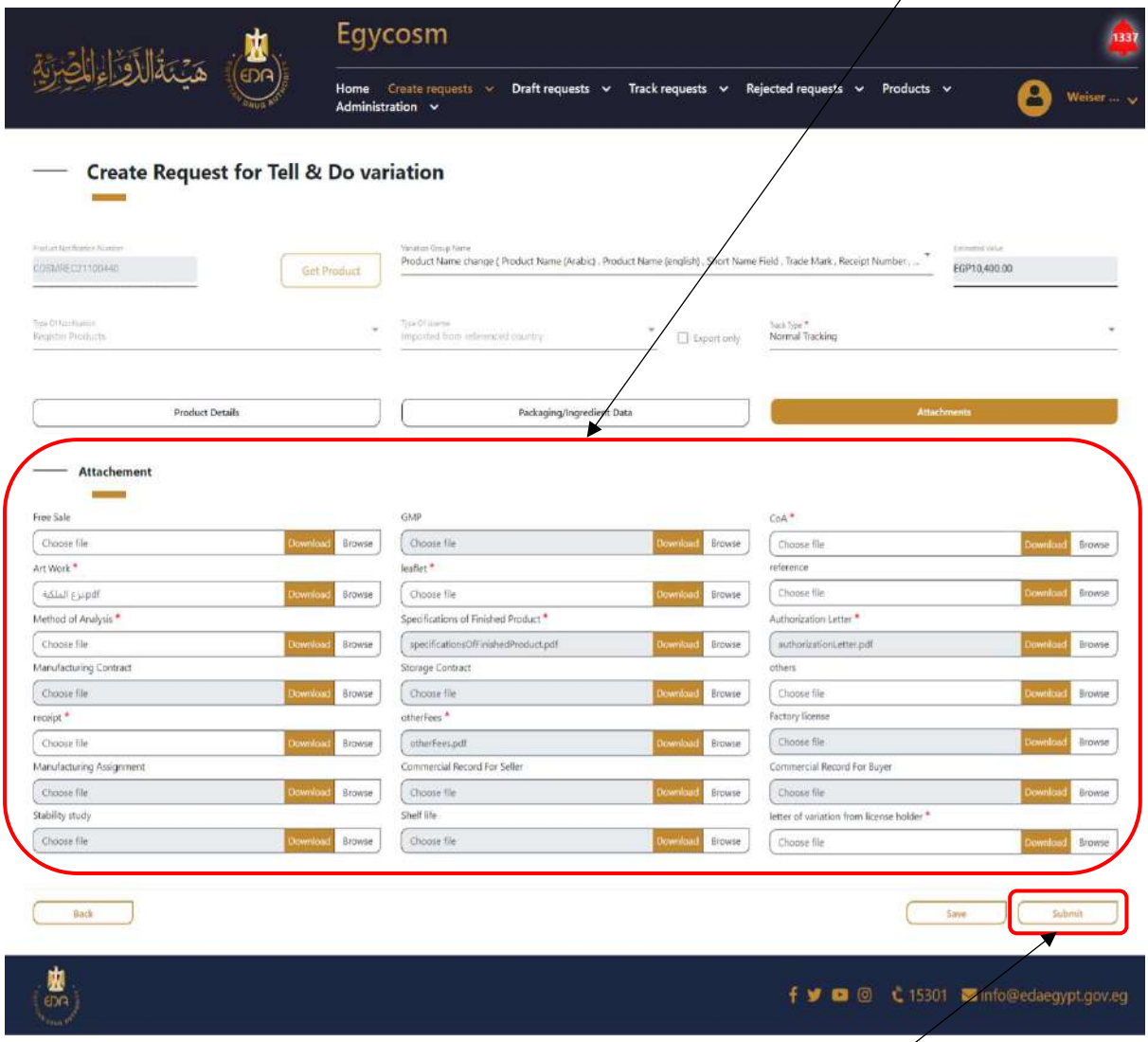


Here are the appeared fields for what we choose from the list in **variation group name,**



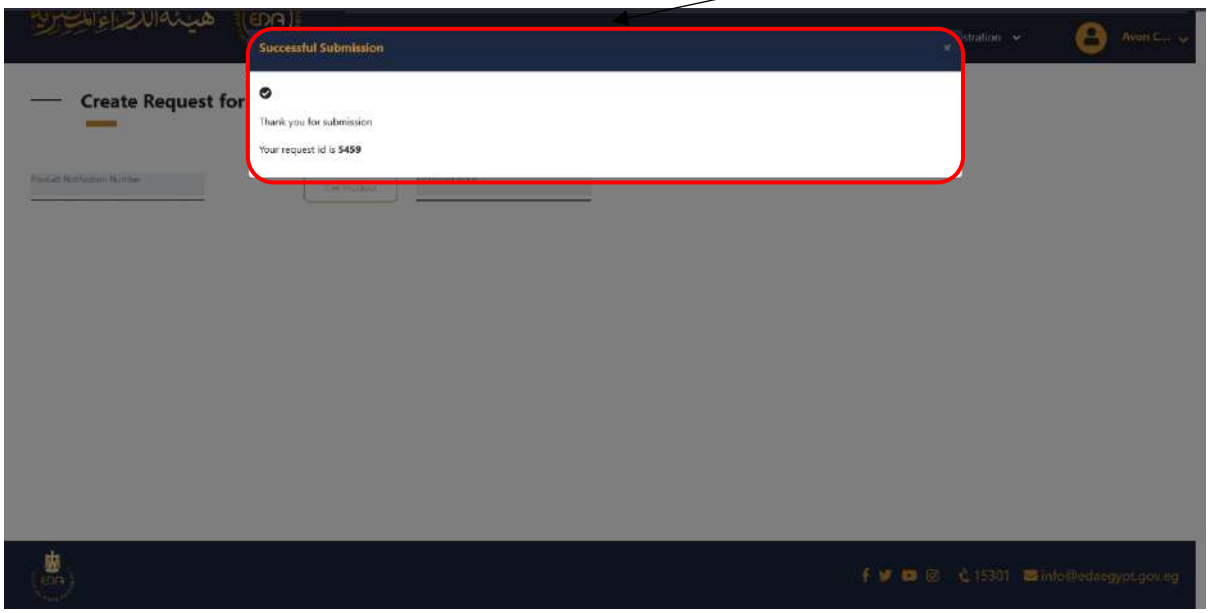
You must fill all the fields which have (*) mark.

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



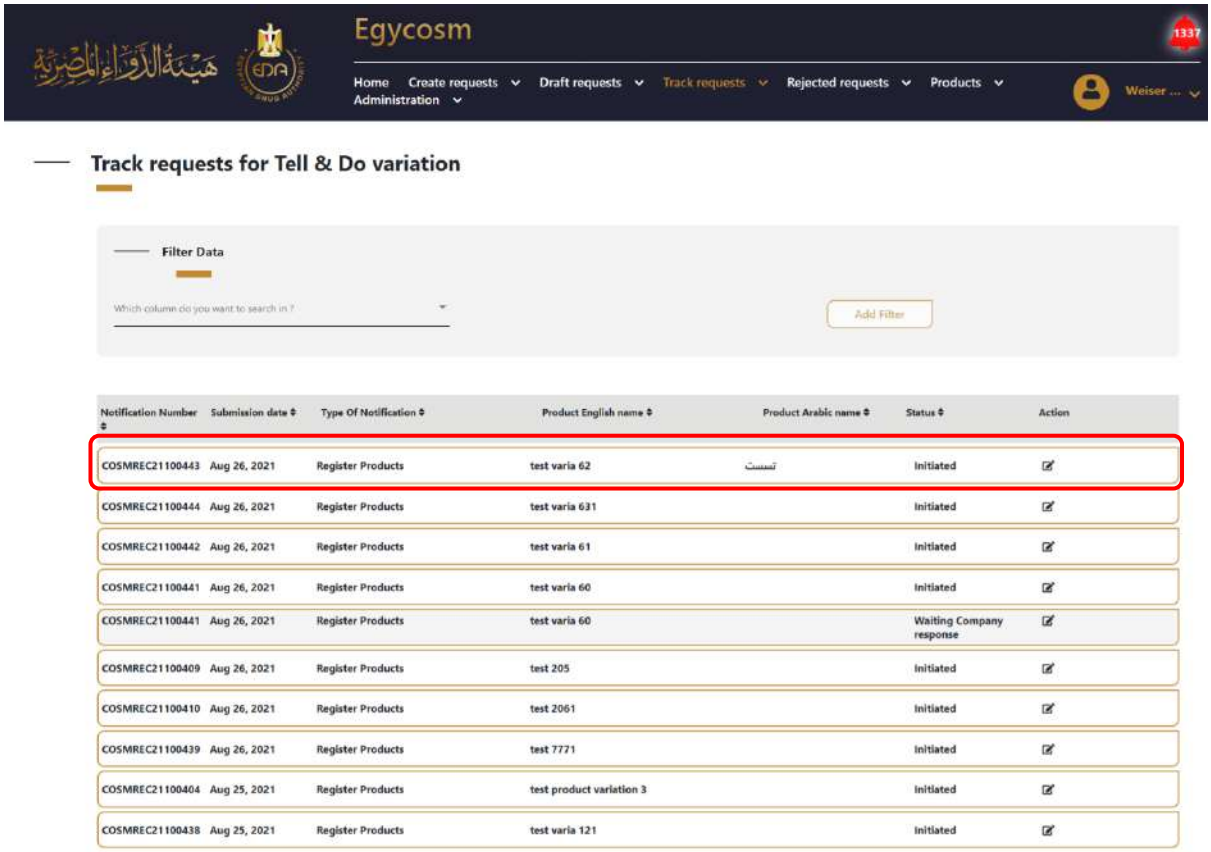
After filling all fields click submit

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

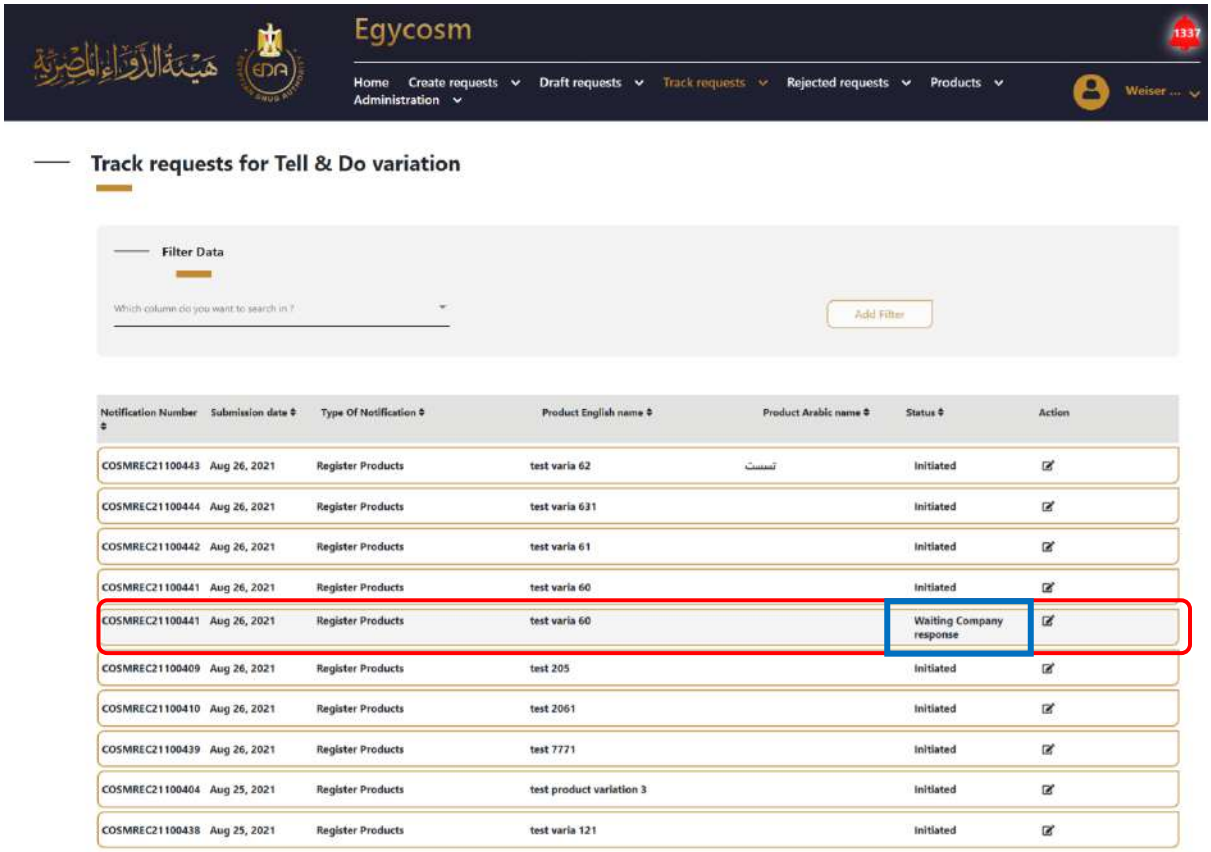


-then we will go to Tell & Do Variation in the Track requests list, and we will find the product appears as is in the below picture.

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



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



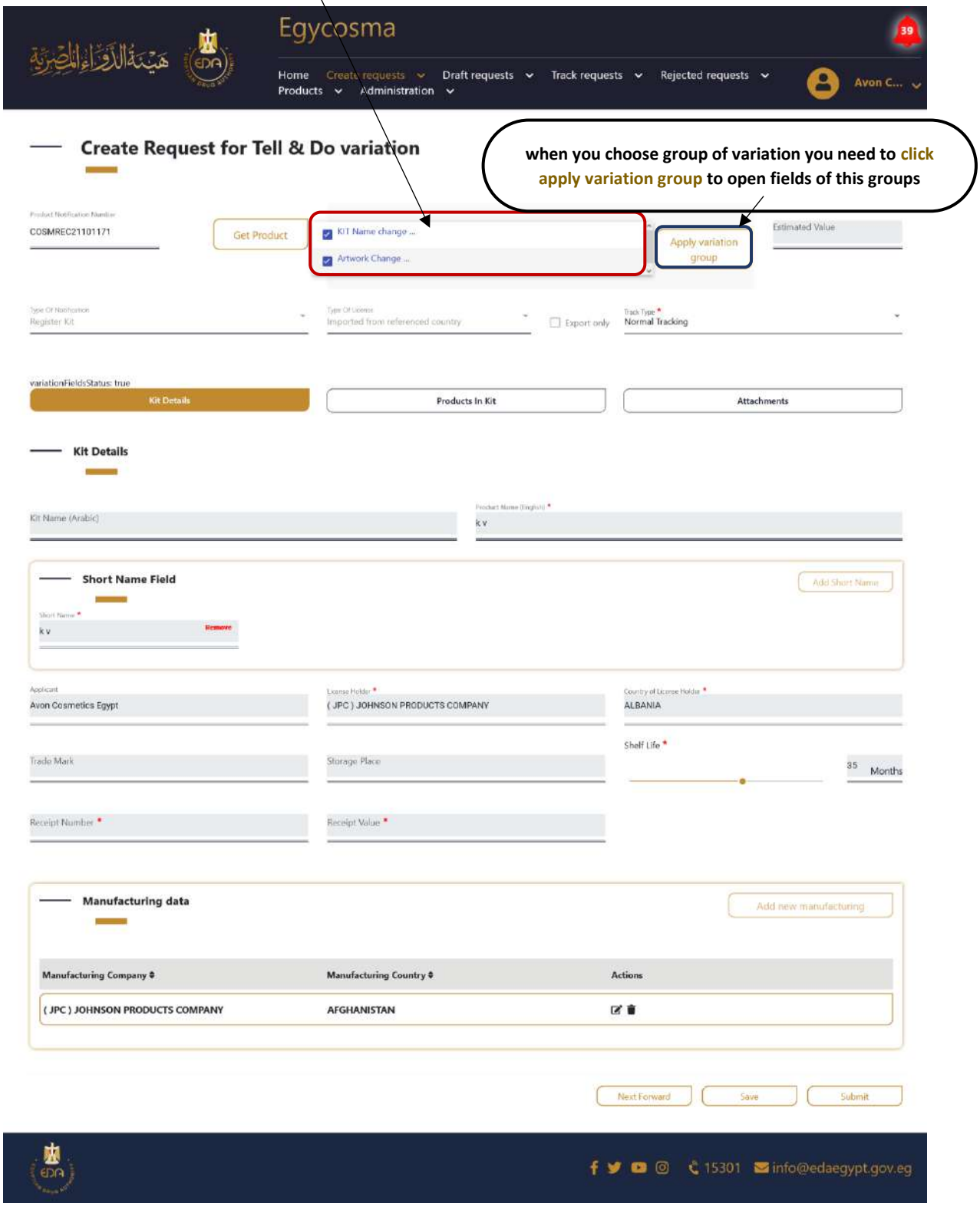
Then after the EDA revision user approve, the product will be moved to the Register Products list as in the picture in the next page.

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

❖ Create request for Tell & Do Variation for (KIT)

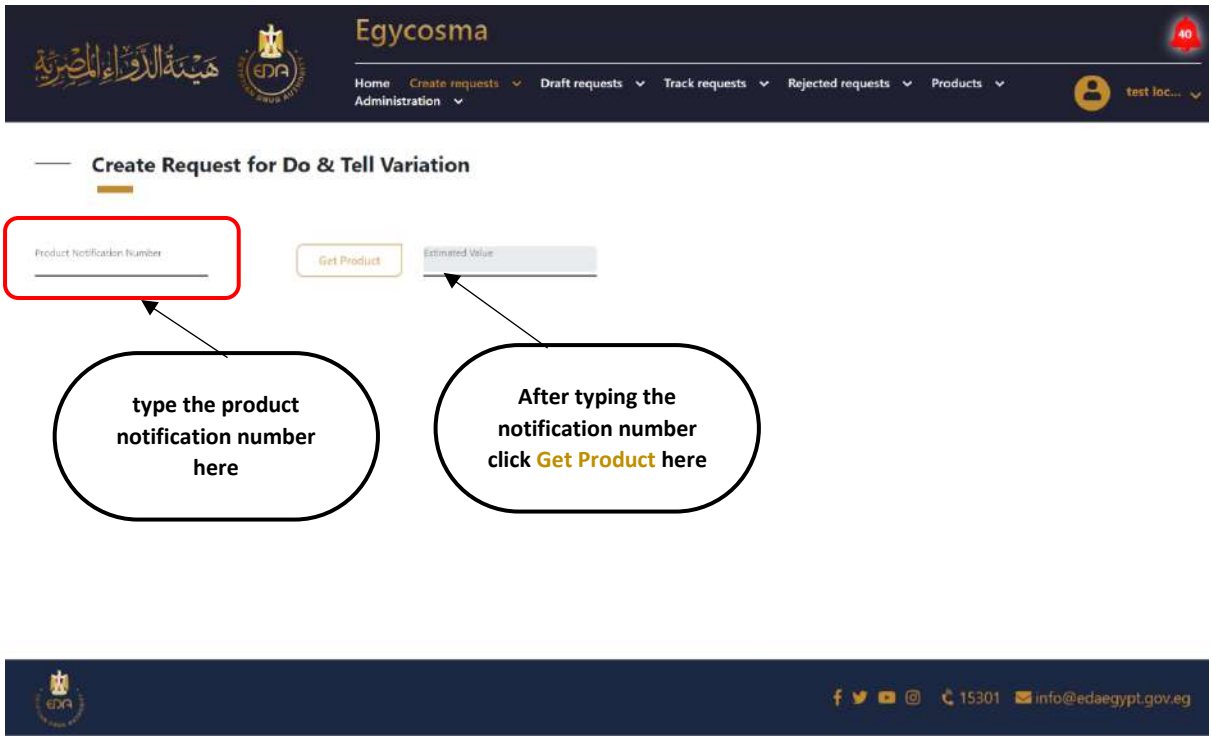
And here if you want to make some changes on a KIT:

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

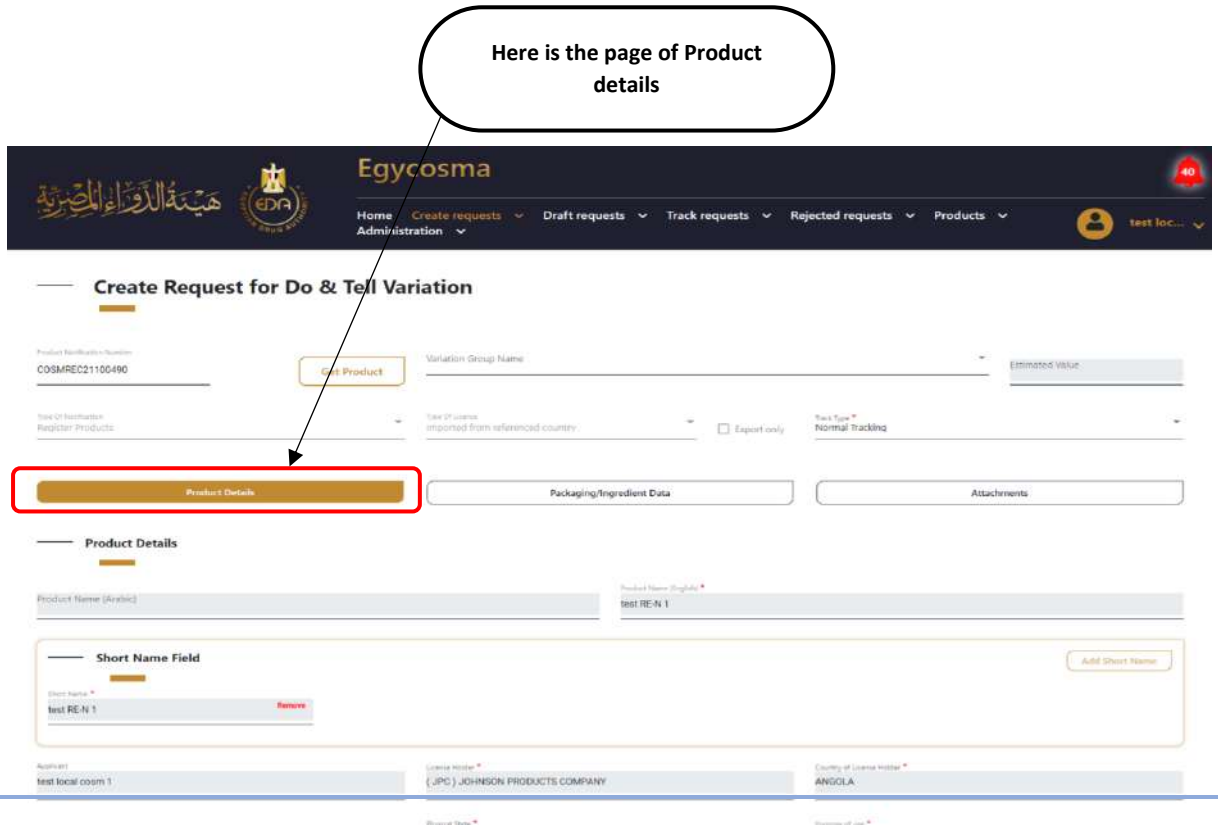


❖ **Create request for Do & Tell Variation,**

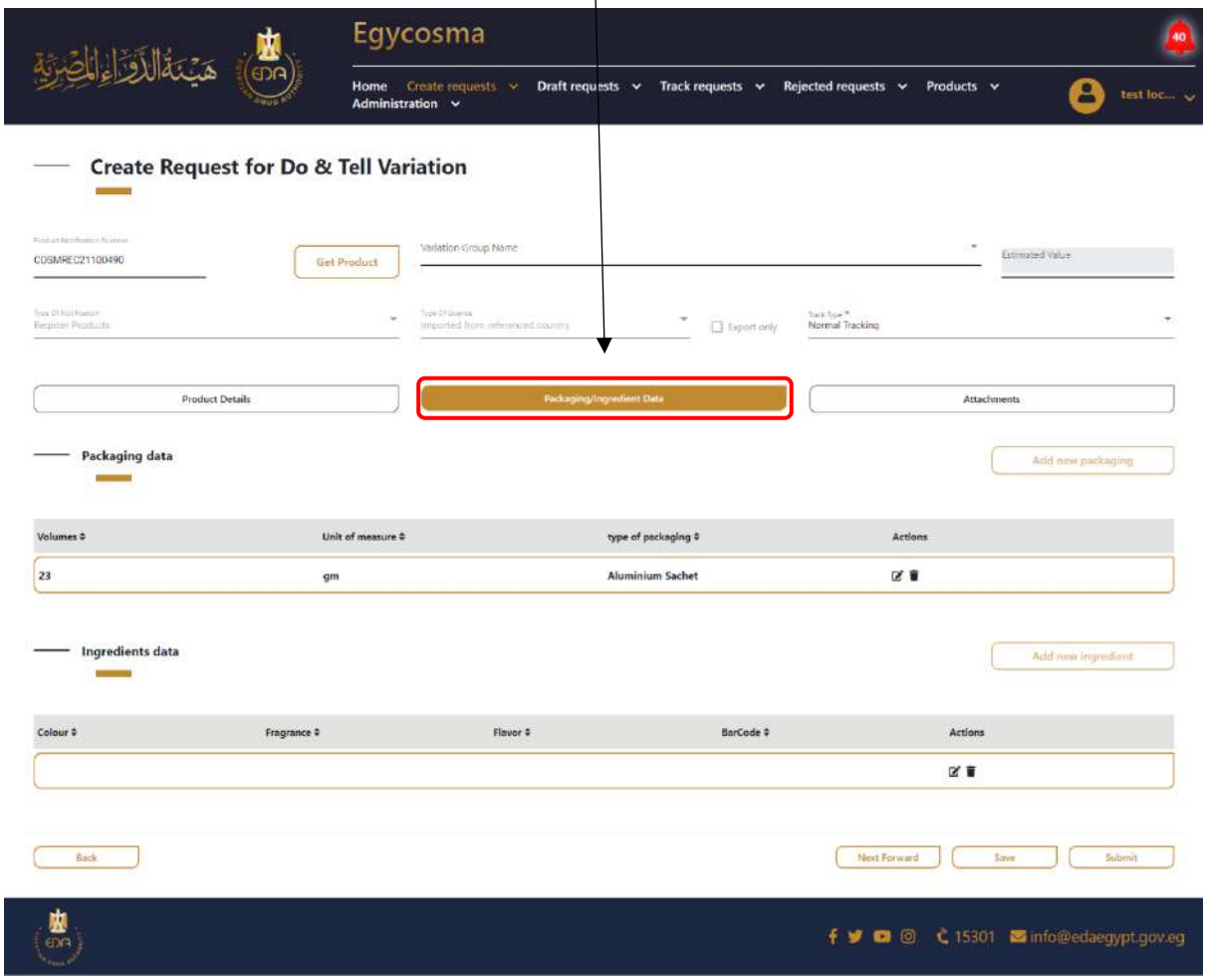
-Select Do & Tell Variation from Create requests list and it will take you to the below page in the picture.



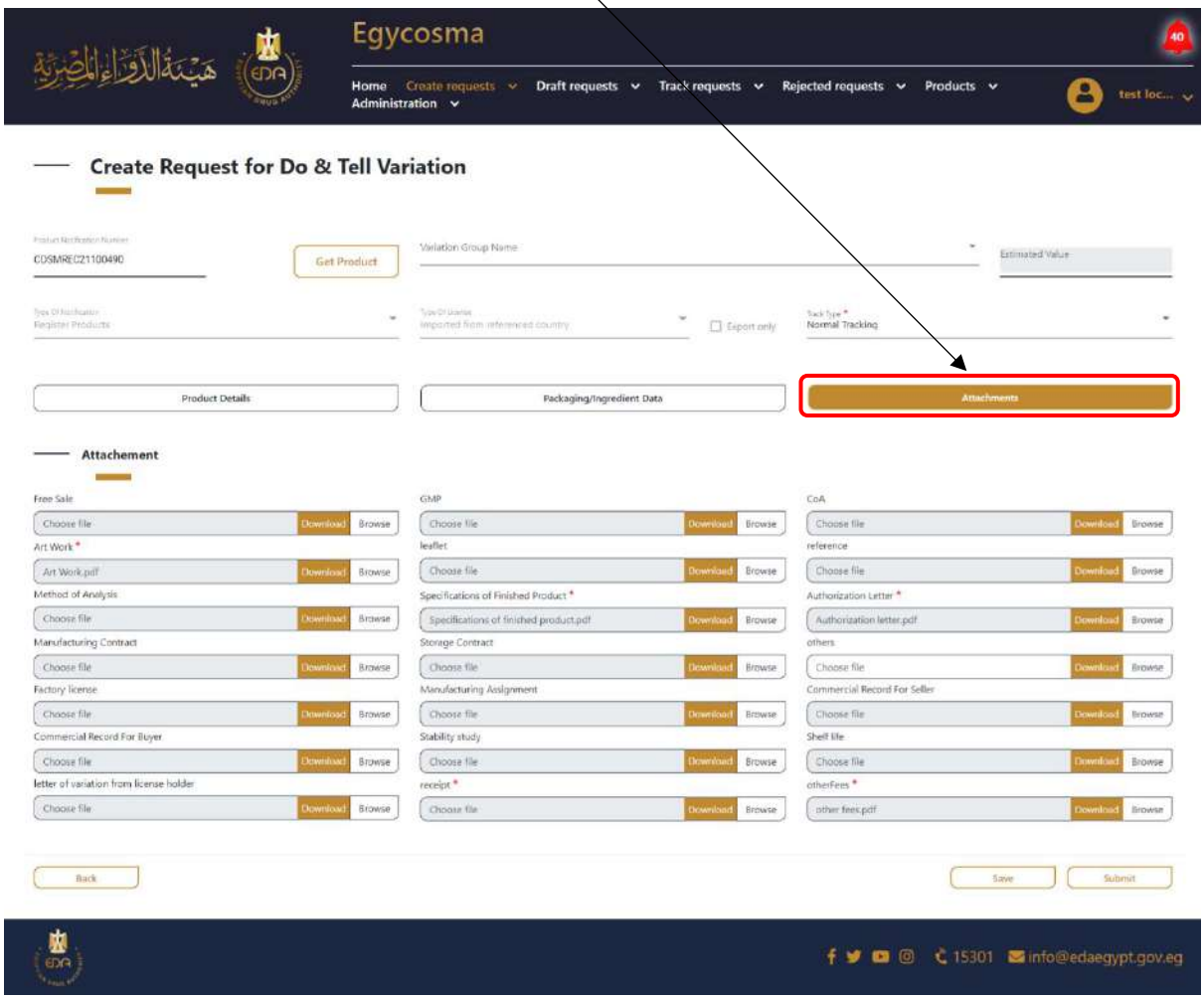
After typing the product notification number, and click Get product, the screen will be as is in the picture in the next page.



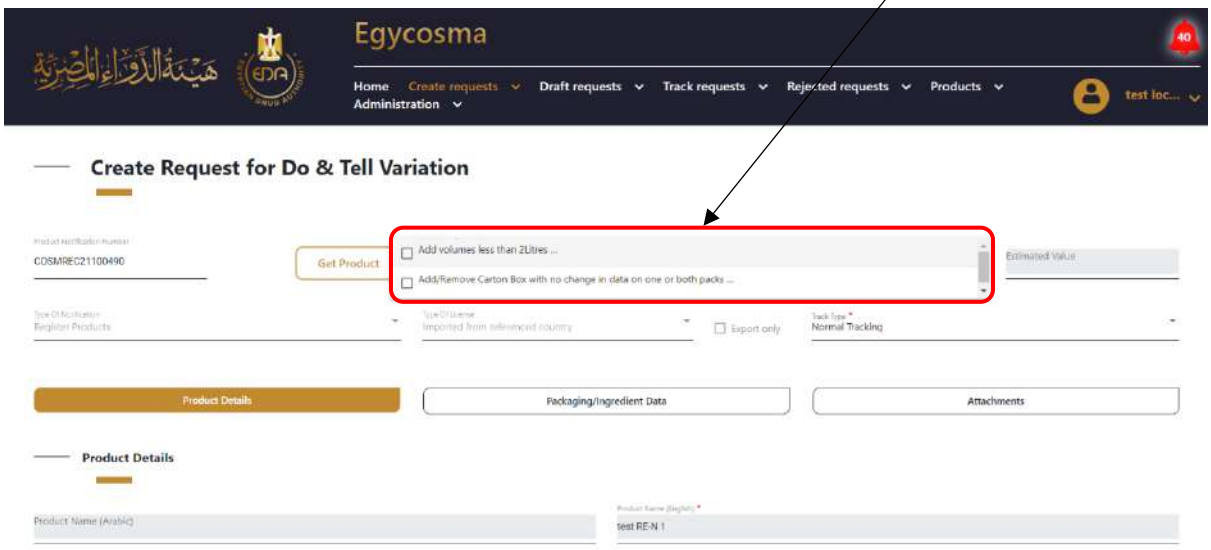
Here is the page of Packaging/Ingredients Data



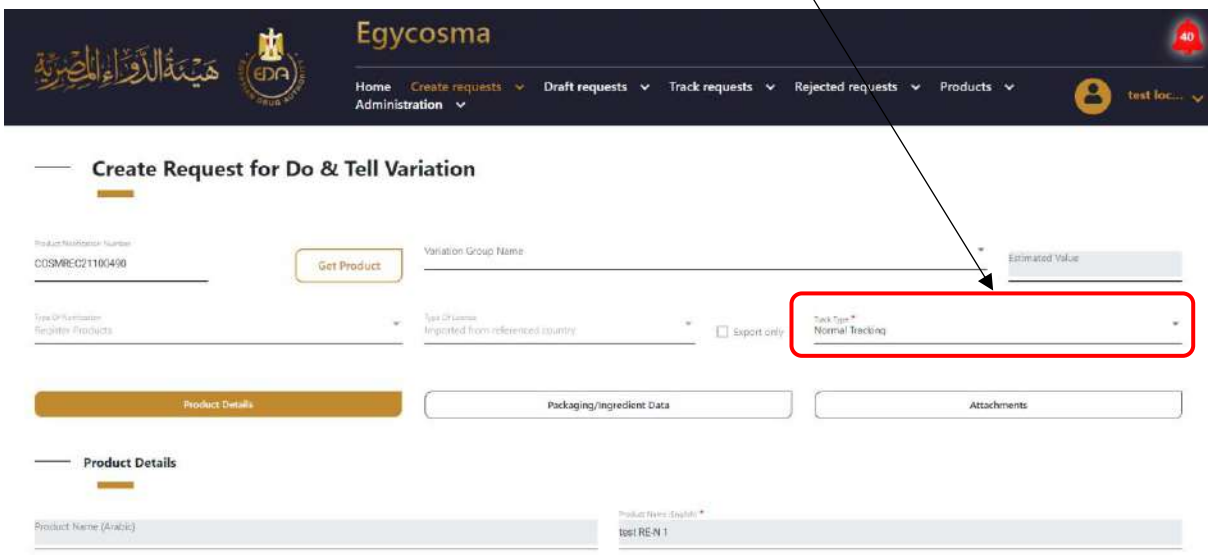
Here is the page of attachment



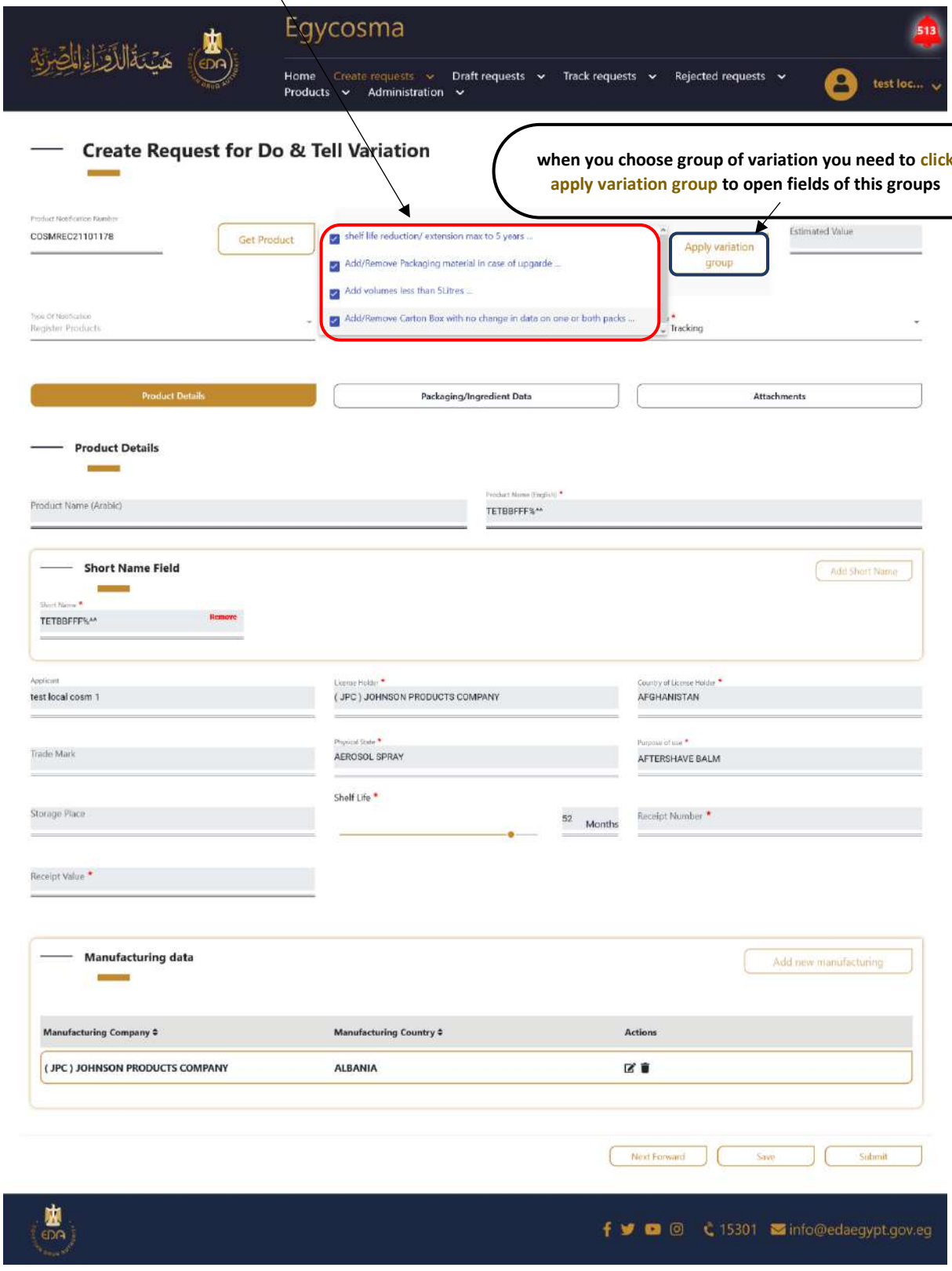
Choose the variation group name from the list here, and please note that the fields which will be appeared in the page are depends on your choices from the list.



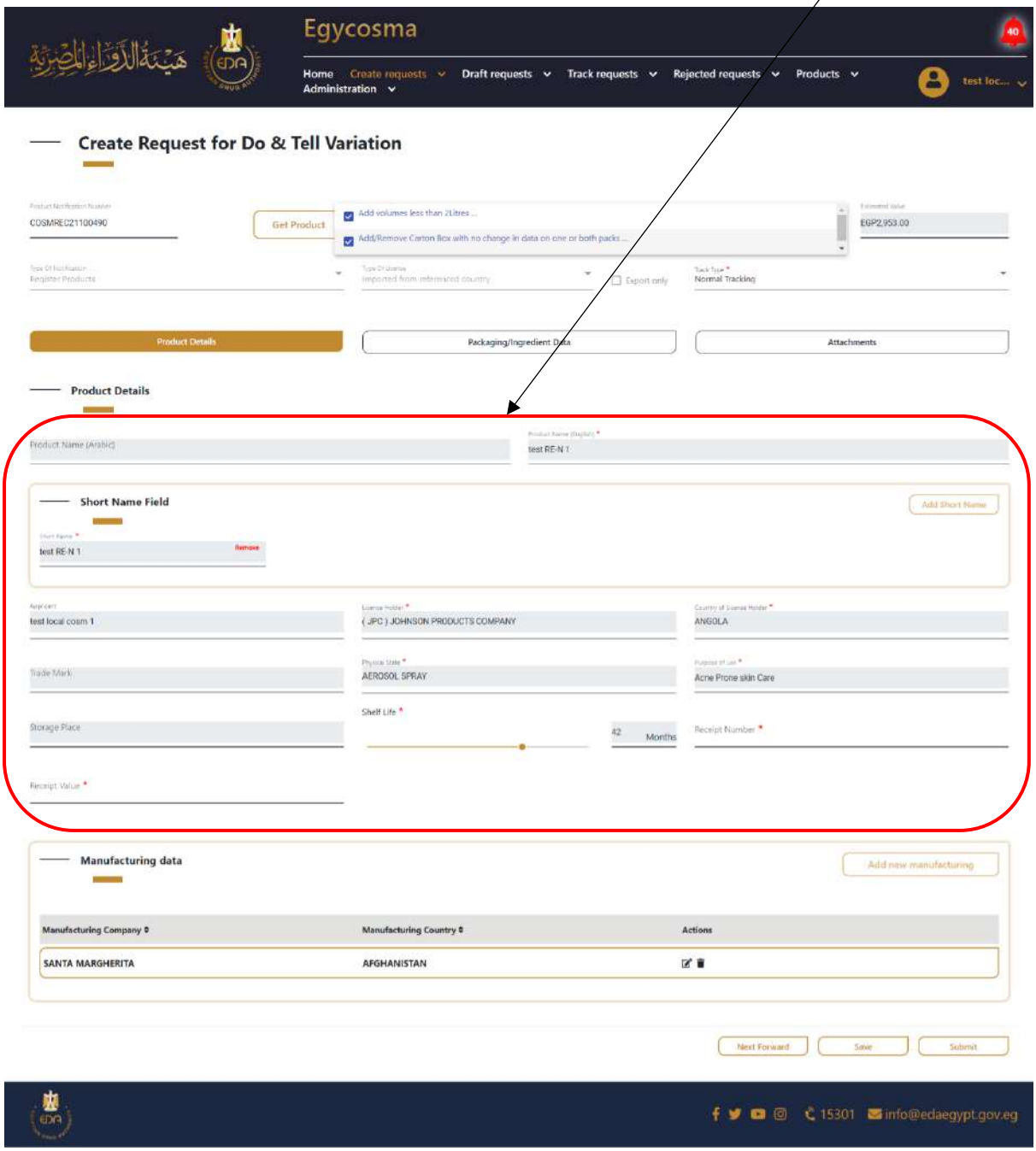
Choose the track from here (normal tracking or fast tracking)



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)

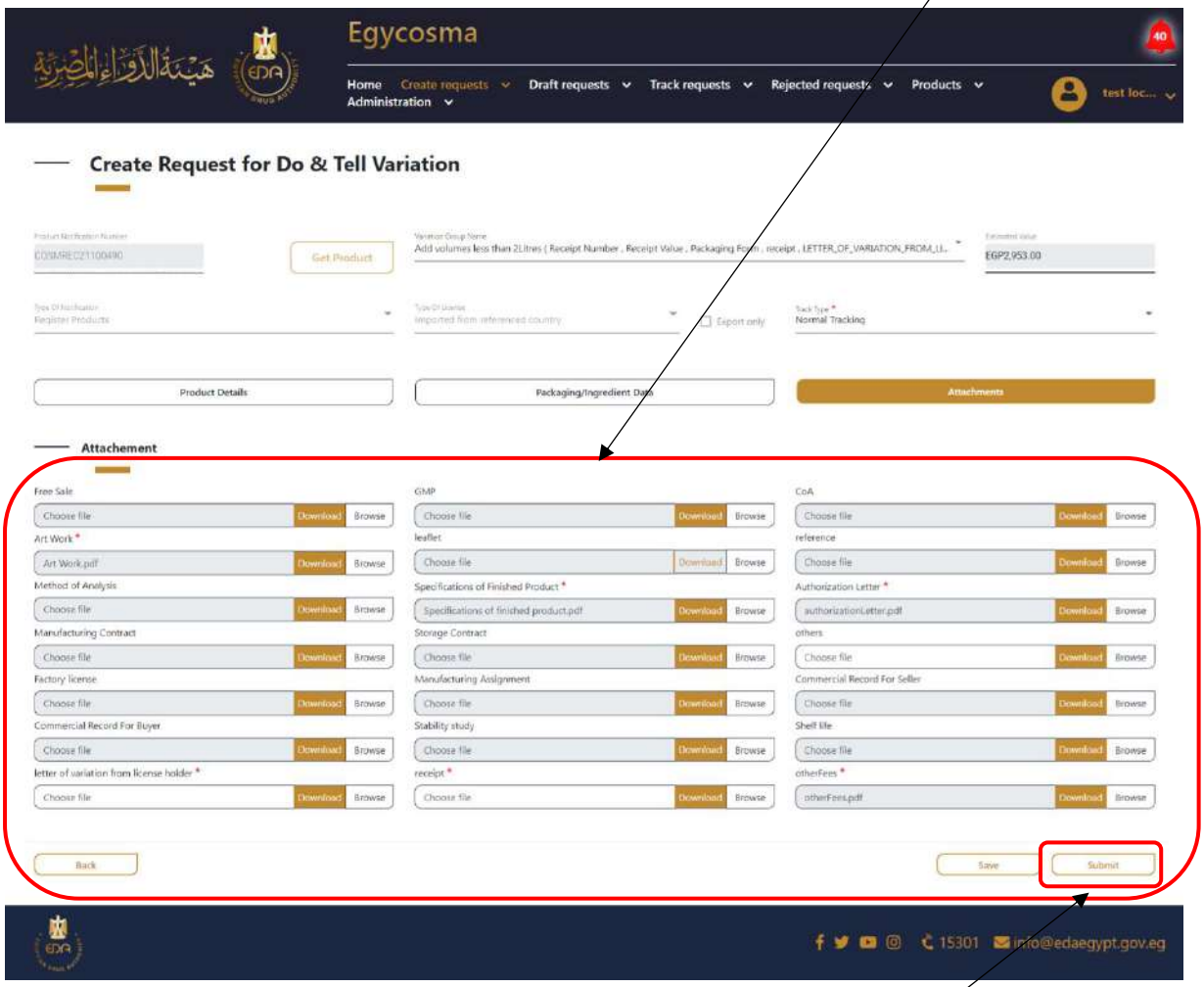


Here are the appeared fields for what we choose from the list in **variation group name,**



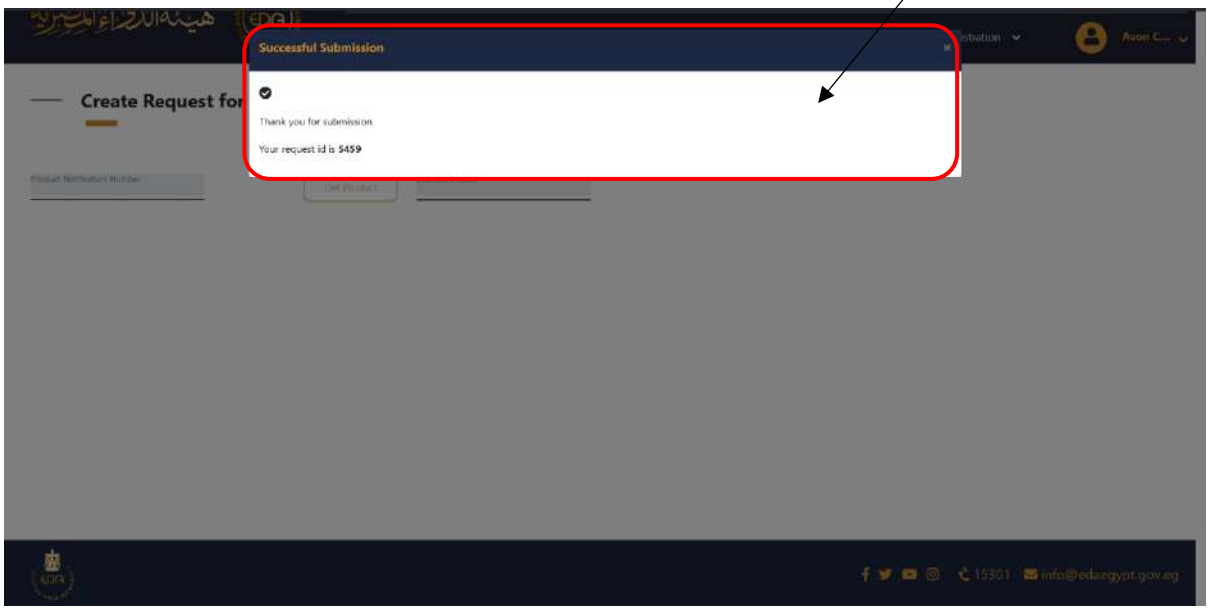
You must fill all the fields which have (*) mark.

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

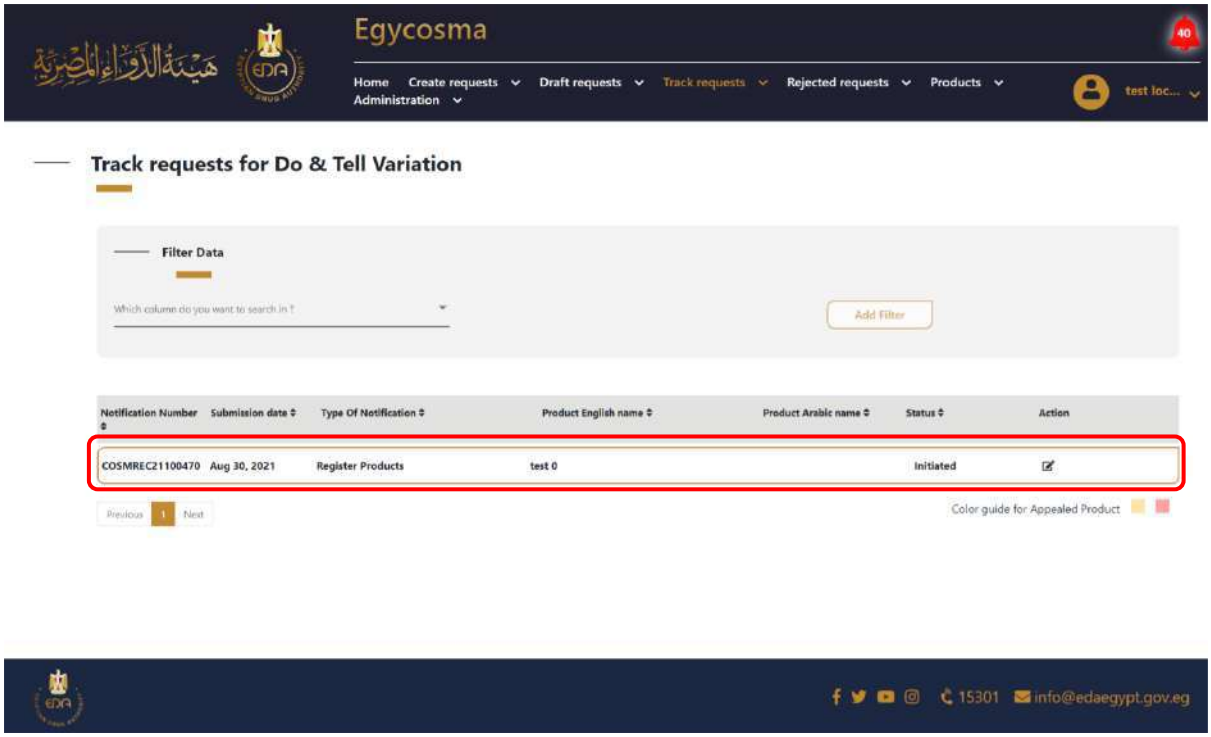


After filling all fields click submit

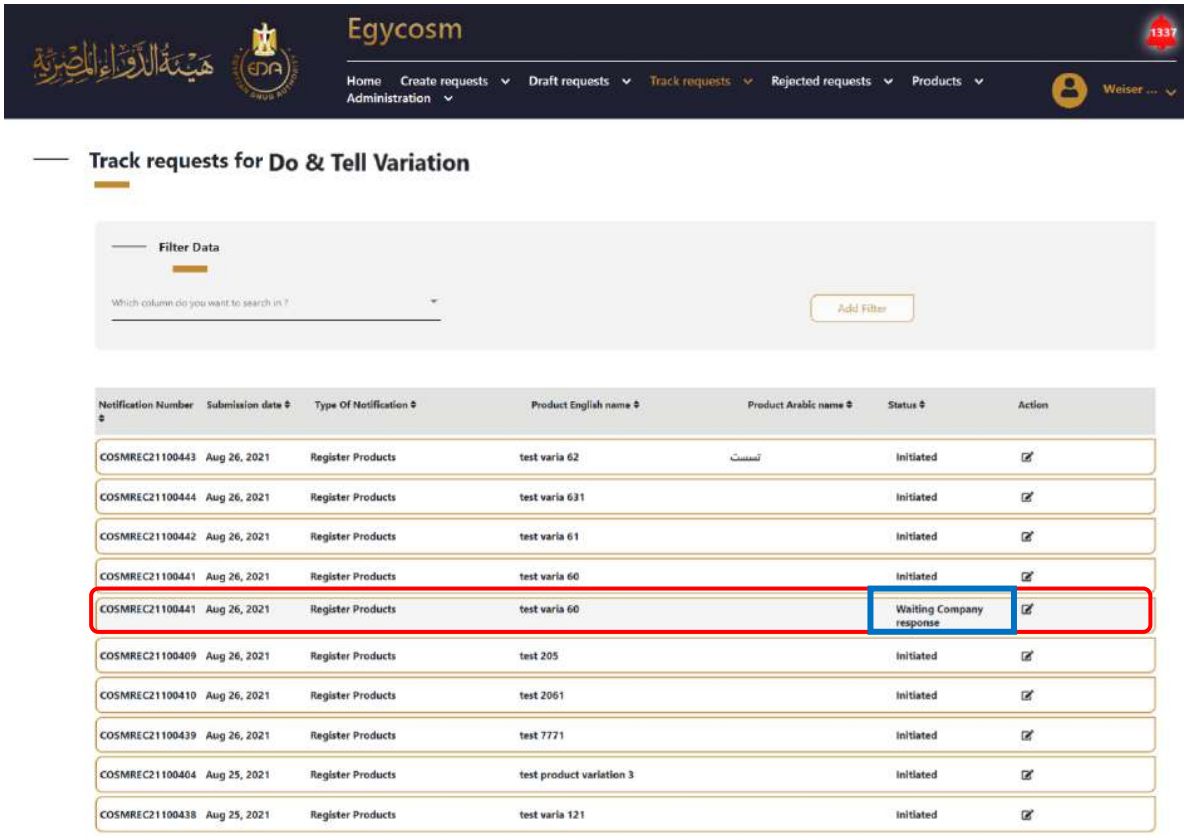
After clicking **submit**, a pop-up message will appear confirmed that your **submission is successfully done**, as appearing in the below picture.



-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.



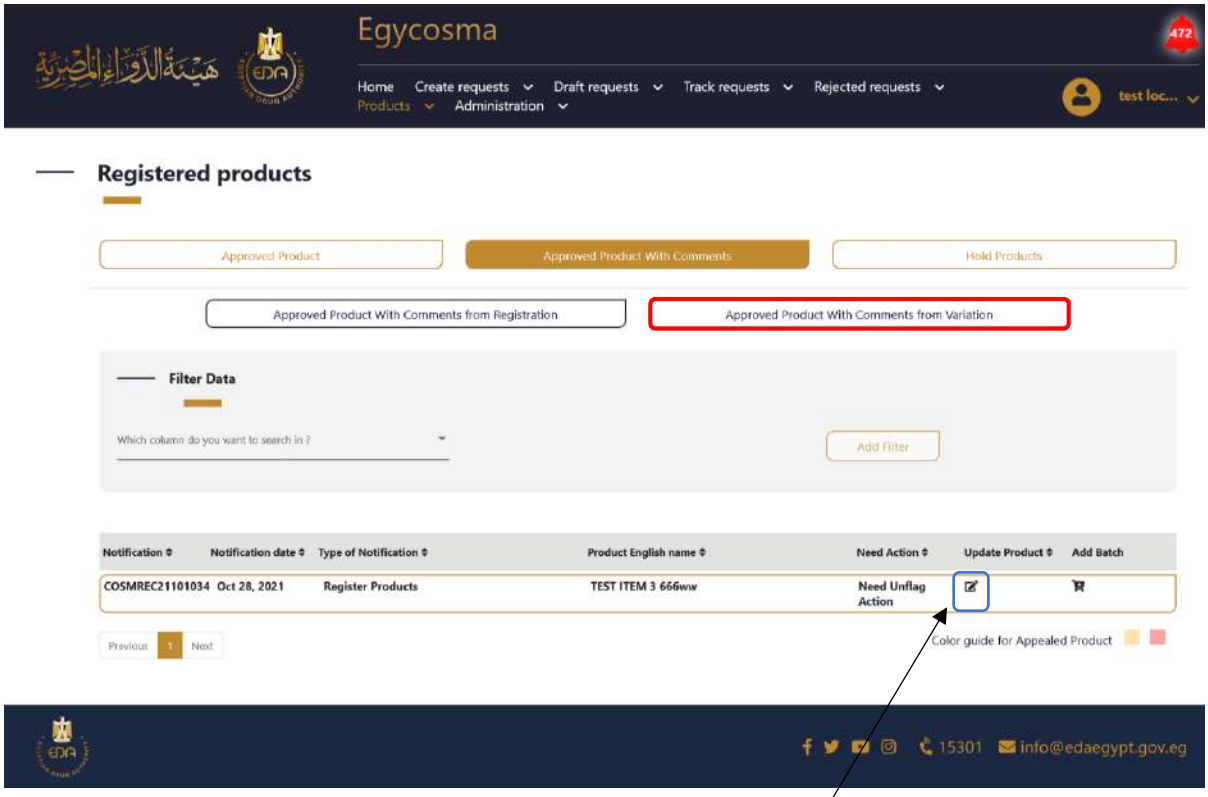
After the EDA revision user approve, the product will be moved to the Register Products list as in the picture below.



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

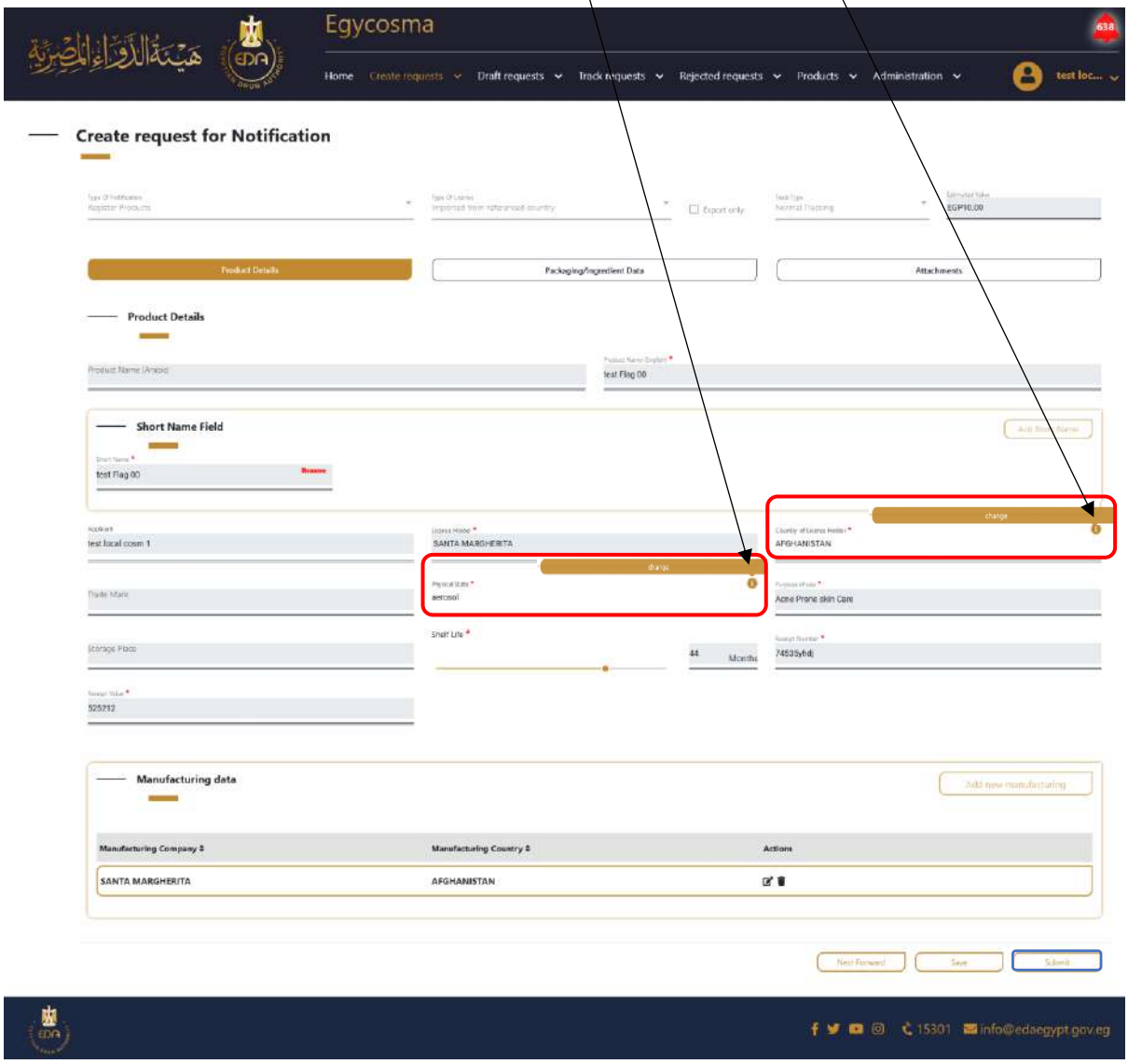
Approved products with comments variation (FLAG) as in the below picture. and these products need (UNFLAG) action

- **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**



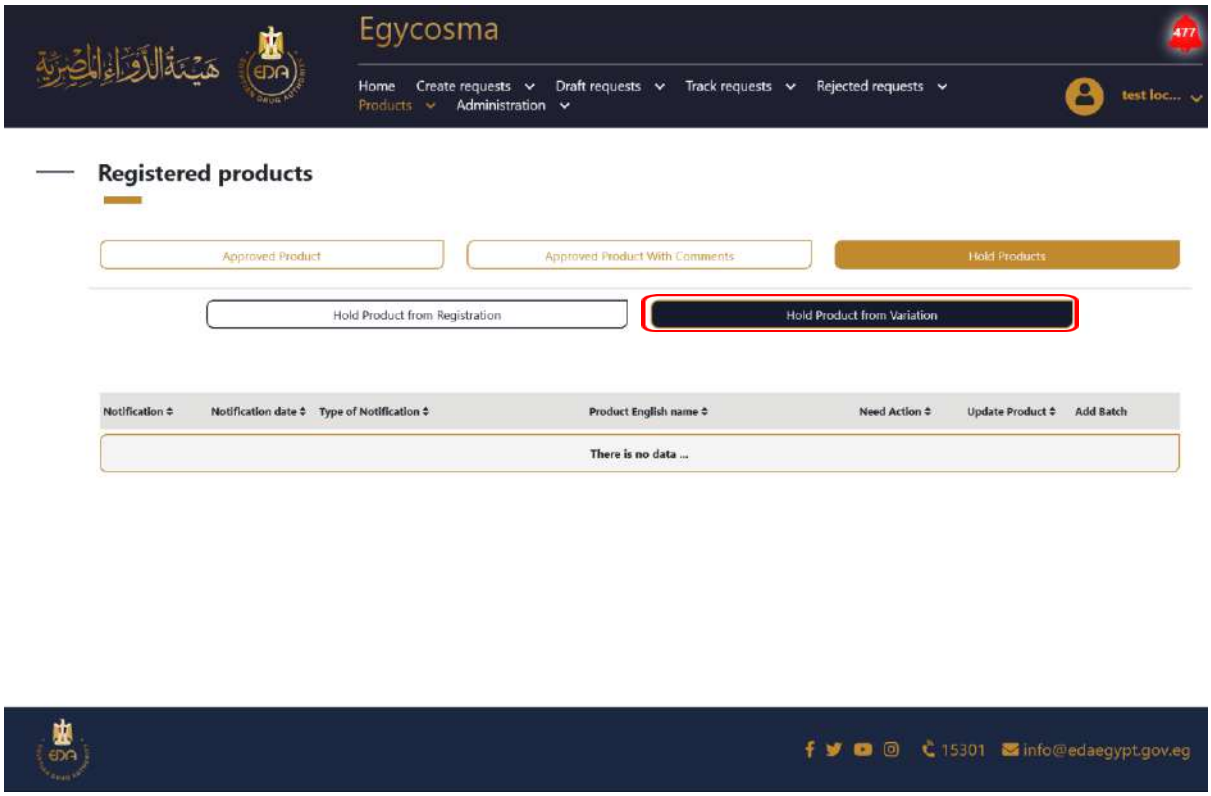
First step clicks on the action icon here, the page will be transferred to unflag product, as appearing in the picture in the next page.

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

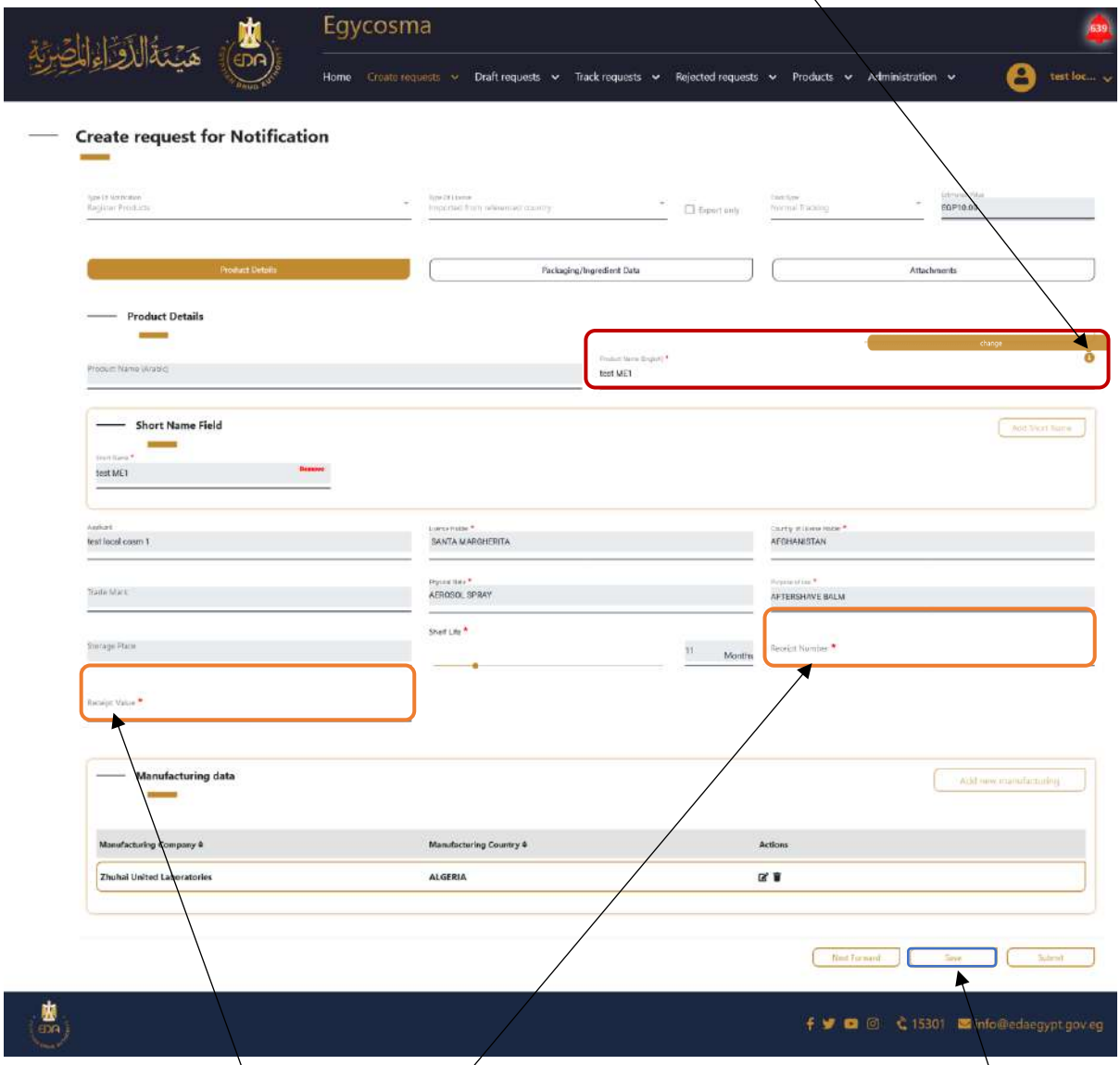


Hold products from variation as in the below picture. and these products need (UNHOLD) action.

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



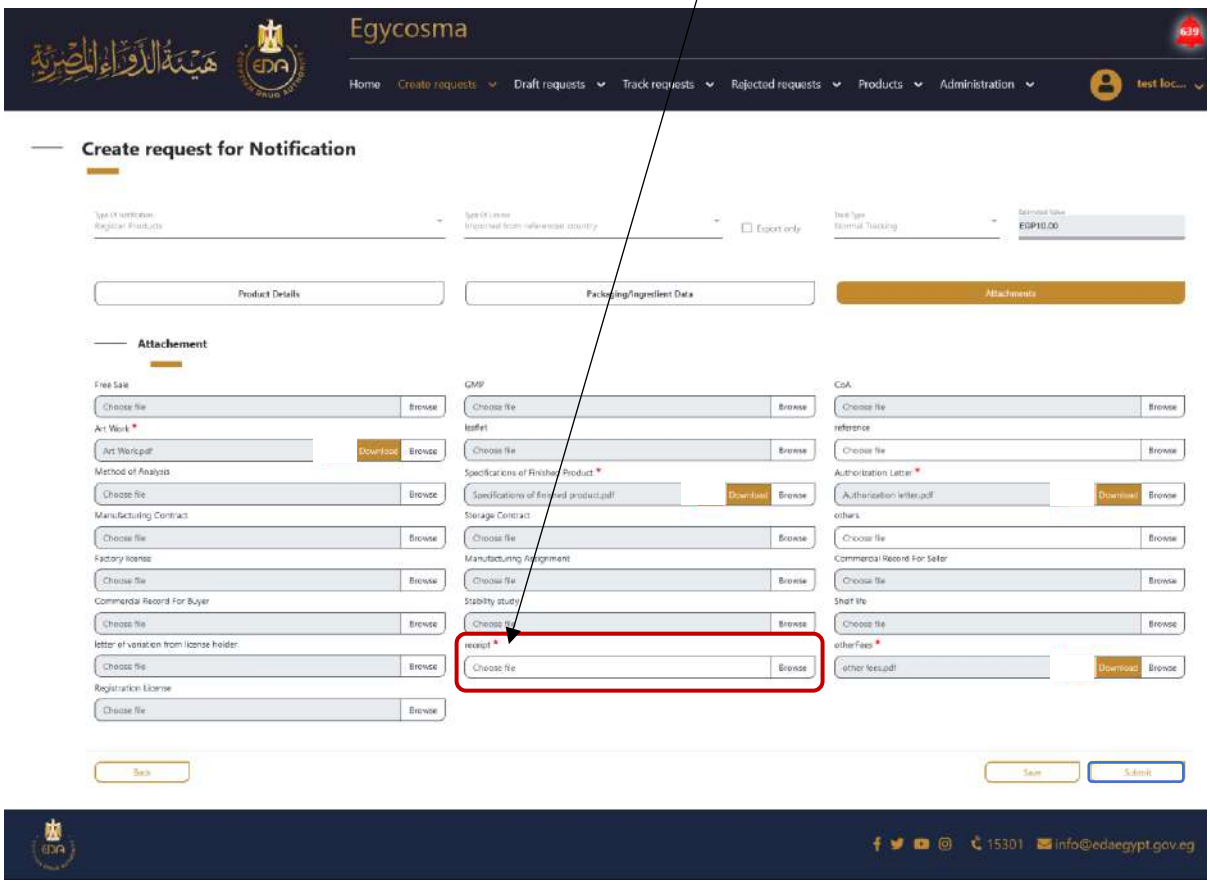
In this step you need to **check all comments**



you have to enter receipt number, and receipt value

You need to save first to enable add receipt attachment

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

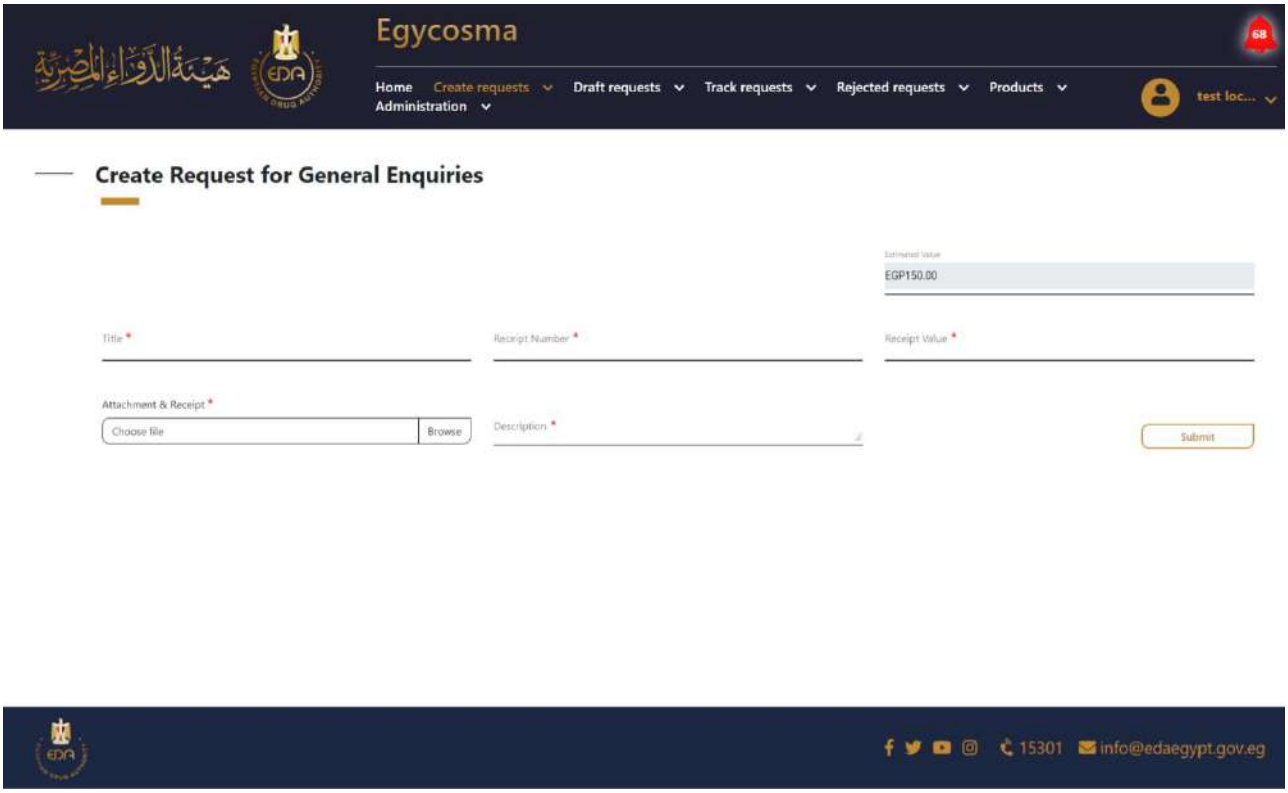


The last step for request rejection Hold of variation

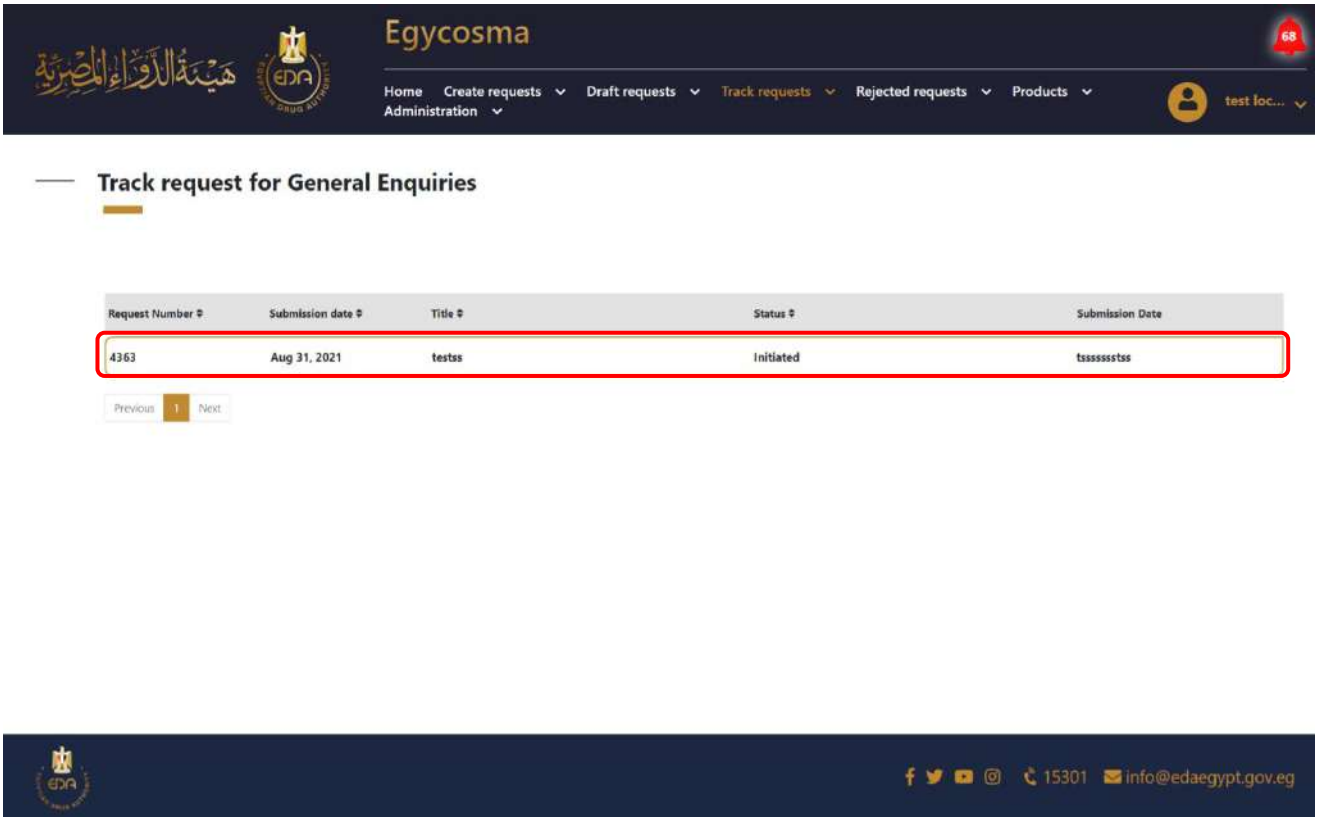
- **company in this step (do unhlold request)**
- **when Authority rejects (the request return in this step) and do unhlold request again (forever)**

❖ **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.



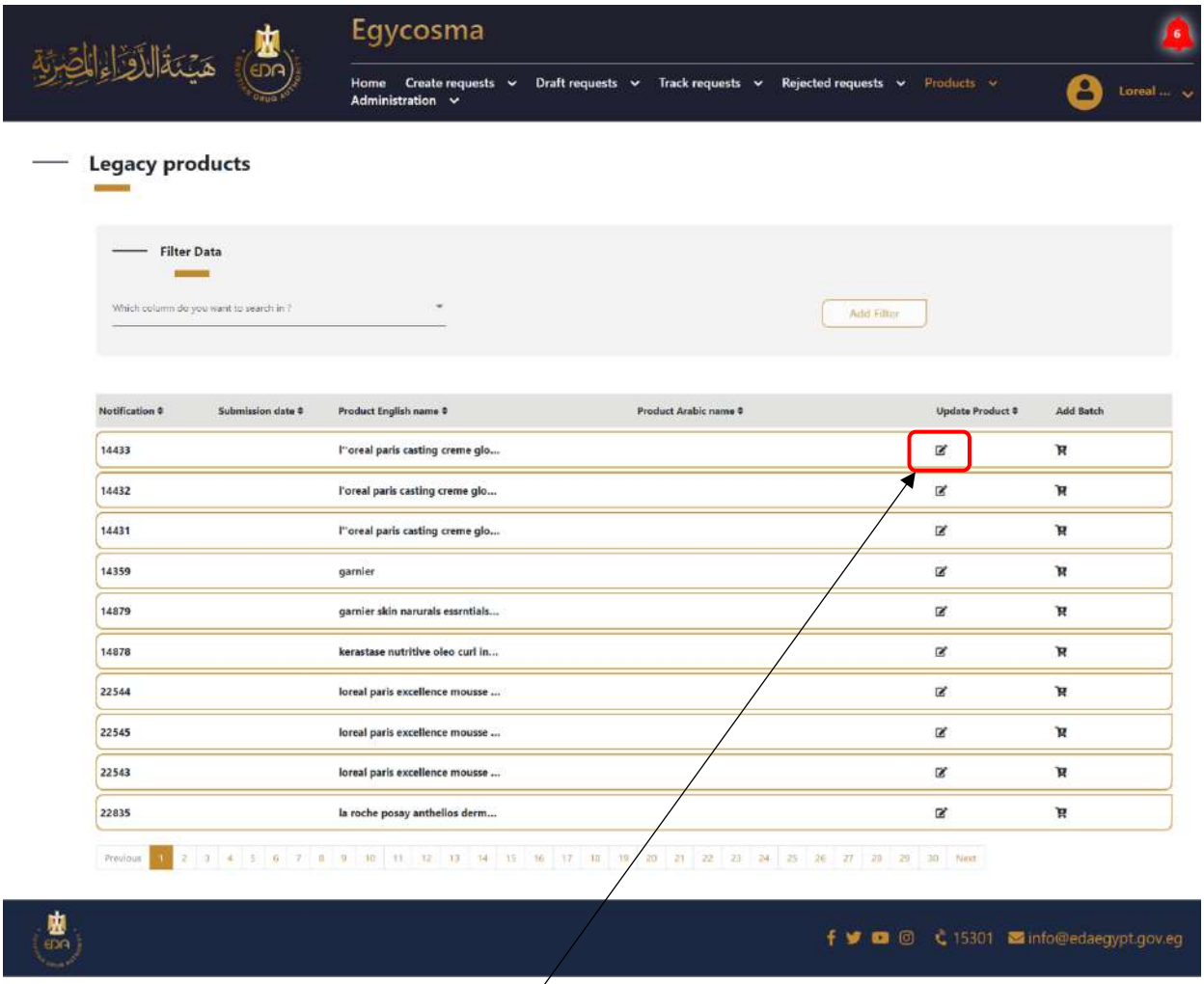
All of the fields are mandatory, after filling it all click submit, then go to Track request list, then click on General Enquiries, and you will find your enquiry as in the picture in the next page.


Egycosma
68
Home
Create requests
Draft requests
Track requests
Rejected requests
Products
Administration
test loc...
Track request for General Enquiries
Request Number
Submission date
Title
Status
Submission Date
4363
Aug 31, 2021
testss
Initiated
tsssssstss
Previous
1
Next
15301
info@edaegypt.gov.eg

❖ Legacy,

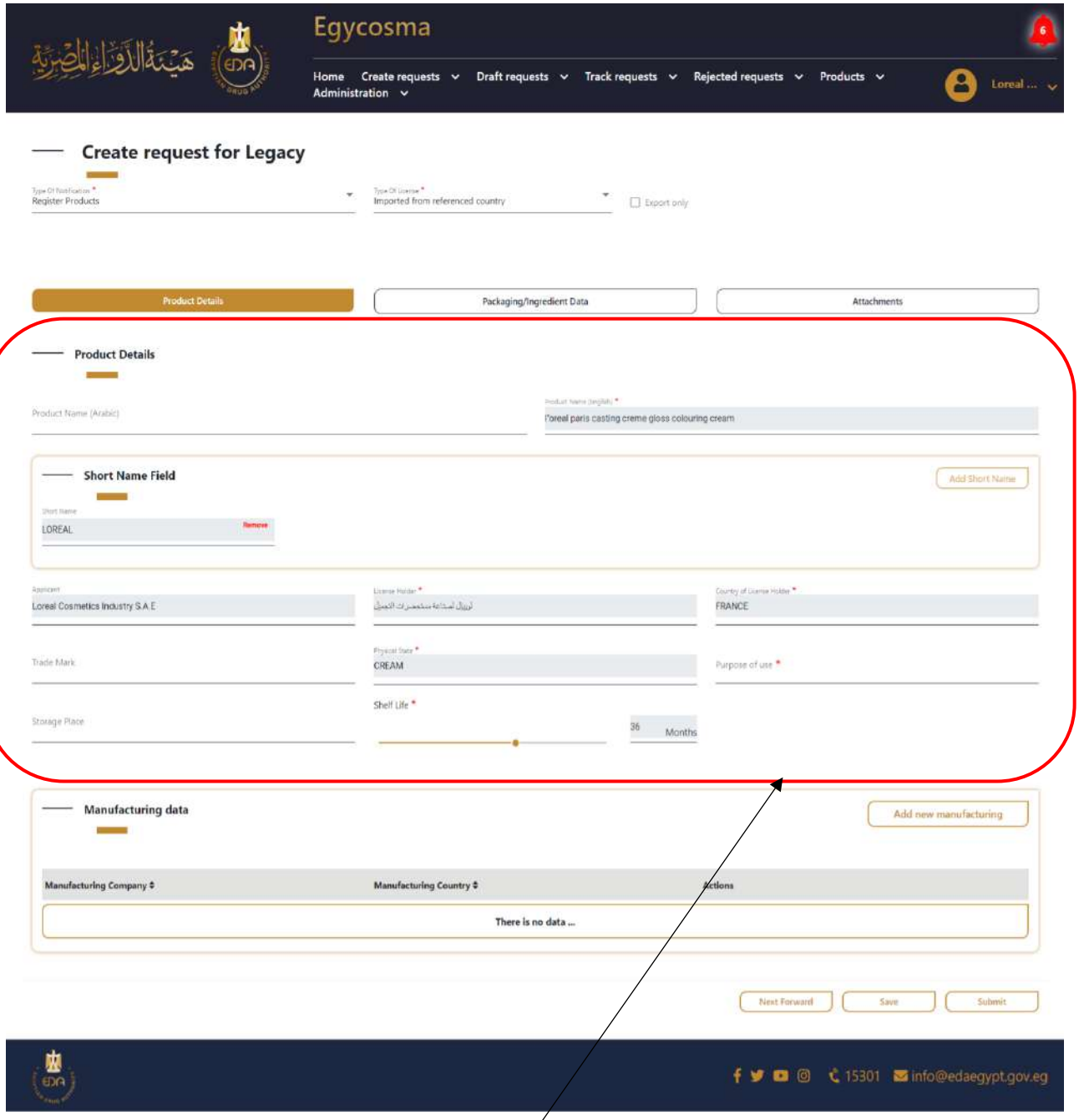
And here you will find all of products that have been recorded and approved before on the system, so you can update any product you want.

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

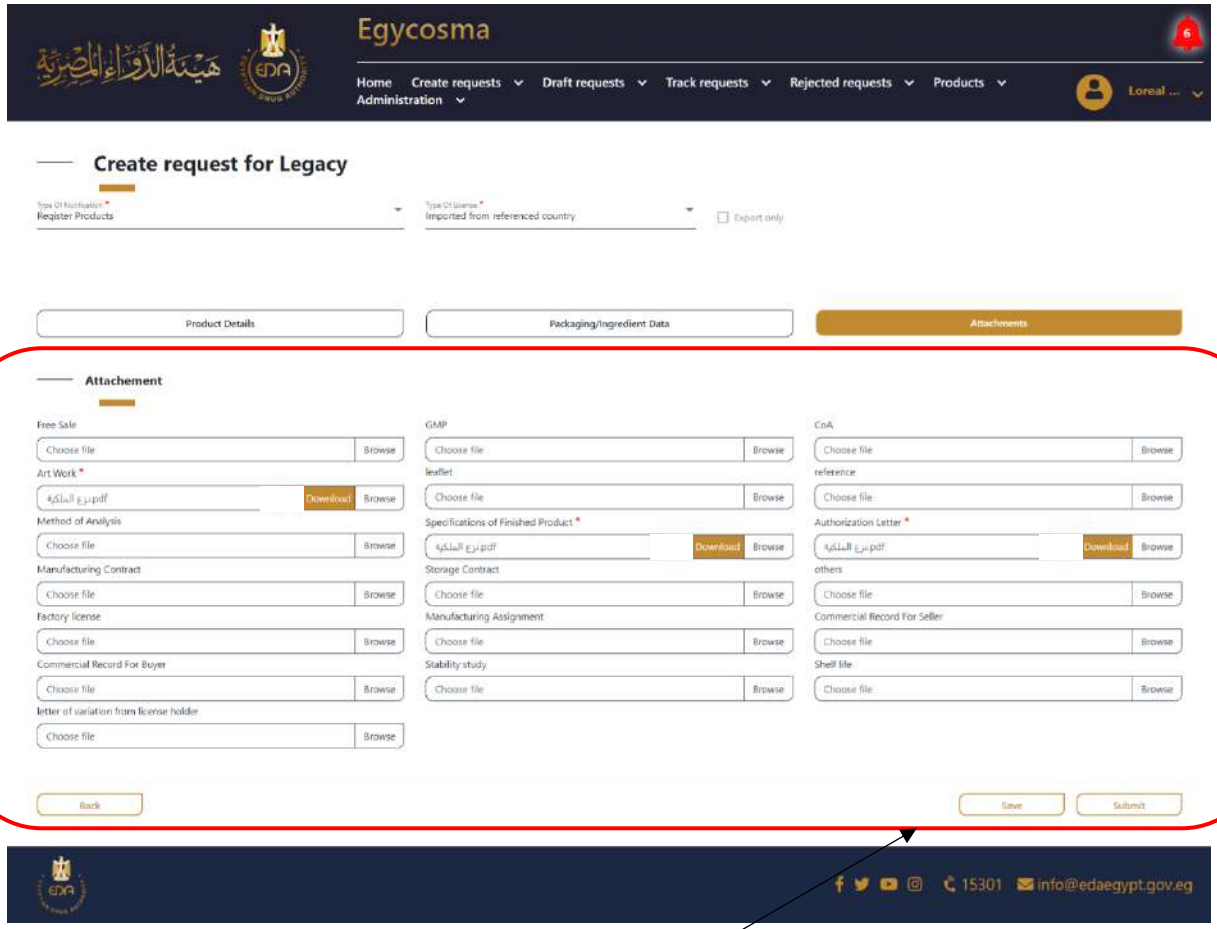


After clicking on update product icon here, the page will be moved to Create request for Legacy, as appear in the picture in next page.

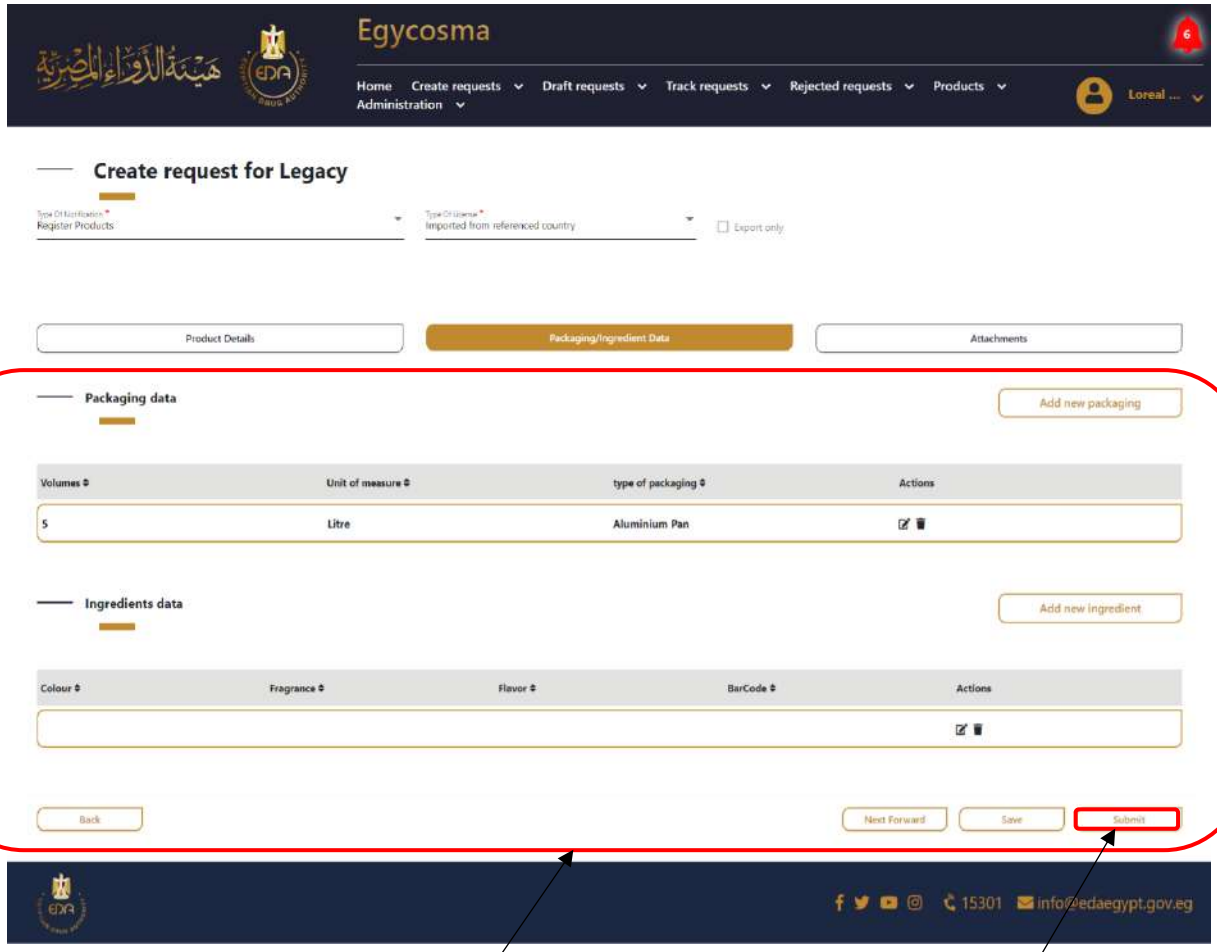
Here is the same process as creating request for notification, so you can fill the fields, and after that click on Submit.



Here are the available fields that you can update it, 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)



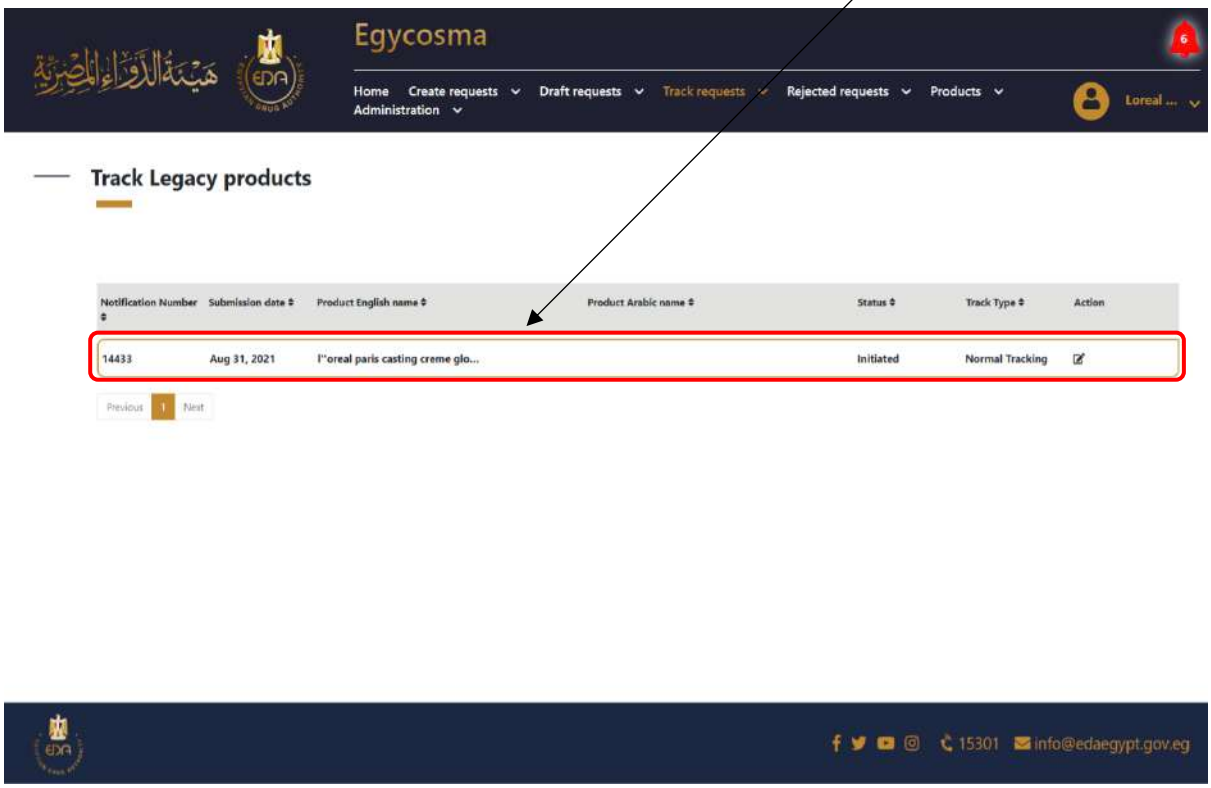
Then go to attachment fields, and upload your documents (must be pdf)



Then go to packing/ ingredients data fields, and update it

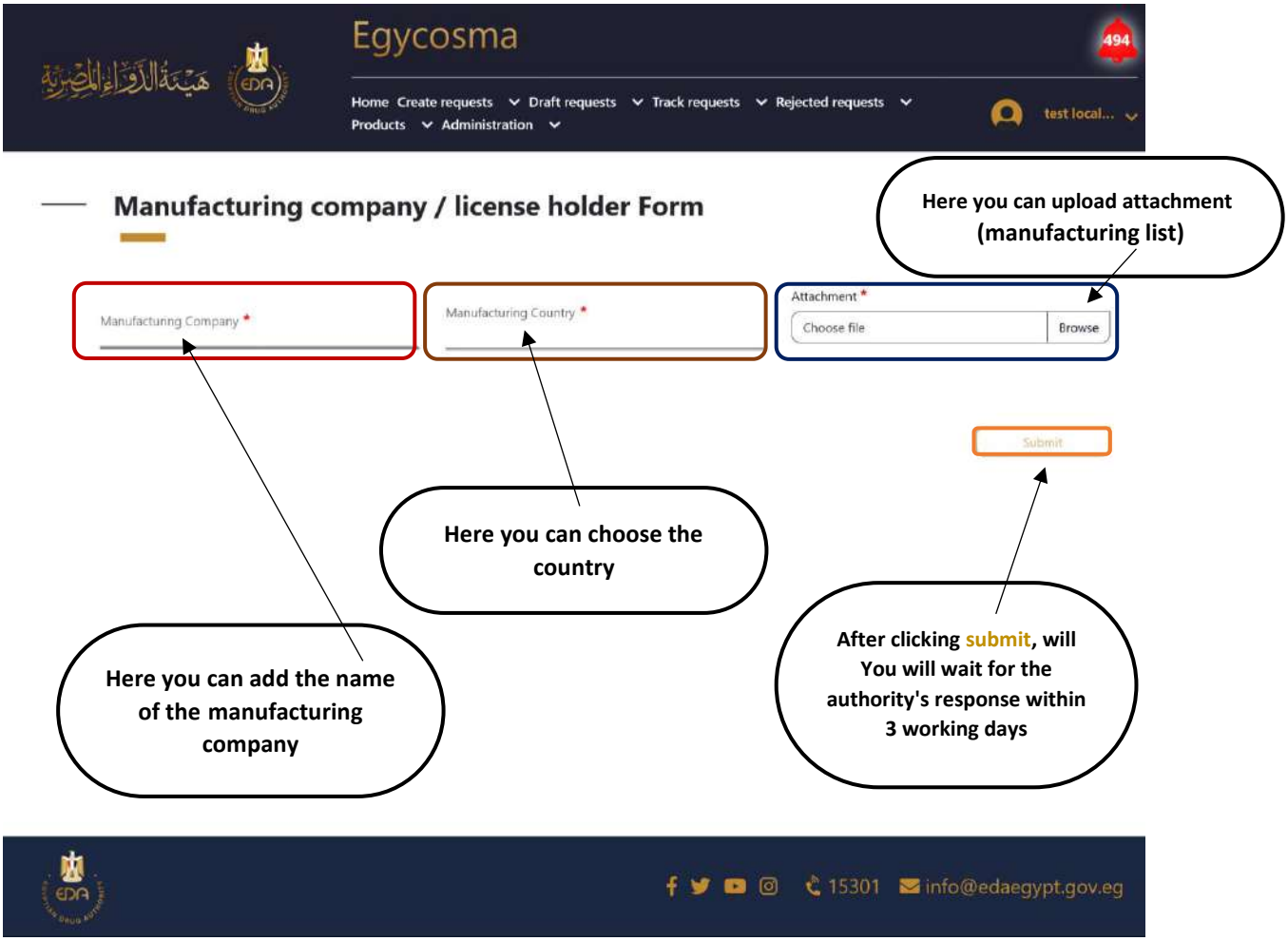
After filling all fields click submit.

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



❖ ADD Manufacturing company / license holder

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



General Notes

- ❖ يجب التأكد من عمل اي متغير على المستحضر قبل التقدم لإعادة الادراج فلا يمكن اجراء اي متغير خلال الإعادة وفي حال وجود متغير اثناء الاعادة يتم رفض الطلب والتقدم لقسم المتغيرات واعادة تقديم طلب الاعادة برسوم جديدة.

- ❖ يجب ان 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 اخرى لا يجوز لكل من الشركتين عمل line extension الا في حالة التنازل عن ال brand كله .

- ❖ في حالة ادراج ال kit يتم ادراج كل مستحضر على حدة ثم التقدم بطلب ادراج ال kit في حال رغبة الشركة

- ❖ يجب التأكد من نوع التسجيل ونوع المستحضر ونوع الطلب وفي حالة خطأ الشركة في تقديم نوع التسجيل (مستورد مرجعي او غير مرجعي او محلي او مصنع لدى الغير) او نوع المستحضر (مستحضر عادي او صبغه او kit) اونوع الطلب (fast or normal) يتم رفض الطلب واعادة تقديمه برسوم جديده.

- ❖ لا يتم تقديم التماس لتعديل بيان التركيب للمستحضرات المستوردة وفي حالة تقديم الالتماس يتم رفضه.

- ❖ يجب التأكد من وجود خط انتاج موضح في رخصة المصنع قبل التقدم للإدراج وفي حالة عدم وجود خط انتاج تلتزم الشركة بتغير مكان التصنيع مع دفع الرسوم المقررة لنقل التصنيع حسب نوع الملف (normal or fast).

- ❖ في حال رفض طلب الادراج للشركة الحق في تقديم التماسين للطلب الواحد ثم يتم بعدها اسقاط الطلب وتقديمه من جديد برسوم جديده.

- ❖ لا يتم اجراء أكثر من عمليه على المستحضر في نفس الوقت.

- في حاله مستحضر approve with comment(flag) لا يتم اجراء اي عمليه عليه الا 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 مده الاعادة لا يتم عمل اي اجراء على المستحضر.

- اي التماس مقدم من الشركة الى الهيئة اثناء الادراج المدة الزمنية المحددة له ٣٠ يوم بعدها يتم اسقاط الطلب ولا يمكن استكماله ويقدم كمستحضر جديد.

- في حاله الاحتكام الى مرجعيه التداول تكون شهادة التداول اجباريه وموثقة من السفارة المصرية.

- وفي حال الاحتكام الى مرجعيه التصنيع تكون قائمه المصانع اجباريه وموثقة من الغرفة التجارية.

- في حاله تسجيل مستحضرات الصبغة او hair colorant kit يجب اضافه اسم الجروب مع اسم المستحضر في long&short name.

- في حالة reject of variation مدة استيفاء ال comments هي ١٥ يوم في حالة الرفض الأولي و ١٥ يوم في حالة الرفض الثانية ولا يمكن للشركة في حالة الرفض الثالث التقدم بالتماس بل يجب تقديم الطلب مرة اخرى برسوم جديدة .

- في حالة ادراج مستحضر متعدد الالوان اوالروائح او النكهات او جميعهم يتّم اضافة مقابل الخدمة التابع لكل فئة الى رسوم الادراج الموضحة في ال Estimated value وفقا لقائمة مقابل الخدمات المقررة .

- تتم مراجعه طلب الادراج وارسال comment للشركة بدون مقابل مادي لمرة واحدة فقط لما يخص استيفاء الطلب لمتطلبات الادراج وفقا للدليل التنظيمي (check list) ويستوجب على الشركة الاستكمال خلال 15 يوم ثم تتم المراجعة الفنية للطلب واصدار القرار النهائي اما بالموافقة وصدور رقم الادراج او الرفض وفي هذه الحالة من حق الشركة الالتماس مرتين للطلب الواحد

- يجب دفع مقابل الخدمات وتسليم اصل ايصال الدفع للاداري المختص قبل ارسال طلب الادراج

- **يجب على الشركة احضار الاصول الموثقة للصيادلة العاملين بالادارة للاطلاع على الاصول قبل رفعها على البرنامج**