



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**

No. **2021-0842**

23 APR 2021

**TO : ALL STAKEHOLDERS AND THE GENERAL PUBLIC**

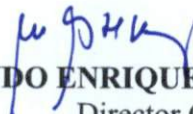
**SUBJECT : Implementation of Food and Drug Administration (FDA) eServices Portal System for Compassionate Special Permit (CSP) Application for Drug Products**

The Food and Drug Administration (FDA), in its commitment to provide stakeholders with streamlined and improved government services, developed the **FDA eServices Portal System** – an online platform for FDA marketing authorization applications.

Please follow Annex A of this Advisory for the Guideline and Checklist of Requirements, Annex B for step-by-step guide, and Annex C for checking of application status via **FDA eServices Portal System**.

The FDA advises and encourages the public to utilize the eServices Portal System for CSP. All individuals or institutions who intend to obtain a CSP are hereby advised to apply through the FDA eServices Portal starting **01 May 2021**.

For any feedback and comments for the FDA eServices Portal, please send it to [cdr.od@fda.gov.ph](mailto:cdr.od@fda.gov.ph).

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General



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## ANNEX A

### Guideline and Requirements for Compassionate Special Permit (CSP) Applications Using eServices Portal System

#### I. Guidelines:

1. All Compassionate Special Permit (CSP) Applications shall be accomplished using the online application form through the eServices Portal System ([eservices.fda.gov.ph](http://eservices.fda.gov.ph)). Creation of account and password is no longer a requirement to obtain access to the online portal.
2. The declared e-mail address under the Contact Information is **unalterable**. The applicant shall make sure that the e-mail address is within the scope and access of the Authorized Person/s and/or Qualified Personnel handling the transaction. Thus, FDA shall not be held liable in any way for loss of access to the declared e-mail address.
3. All fields on the online application form have written warnings/pop-ups/ reminders before proceeding to the next step to ensure the accuracy of information provided.
4. The result of the application will be sent to the email address of the applicant.
5. Documentary requirements shall be in pdf with 5 MB maximum file size.
6. All information filled-out by the applicant during the process shall be reflected in the final output based on the consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filling out all the required information.

#### II. Application and Post-Approval Commitment Requirements:

1. Named Patient Use
  - a. Accomplished online Application Form
  - b. Curriculum Vitae of the Prescribing Doctor
  - c. Medical Abstract of Patient
  - d. Medical Prescription
2. Institutional Use
  - a. Accomplished online Application Form
  - b. Rational for the Volume Requested
  - c. Proof of NRA Approval (for emergency use drug only)
  - d. Distribution Agreement (for emergency use drug only)
3. Post-commitment Reports
  - a. Clinical Study Report
  - b. Reconciliation Report
  - c. Manufacturing Data



### **III. Pre-assessment**

1. An FDA evaluator/assessor shall conduct pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The FDA shall inform the applicant through the registered email address the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. If the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance e.g. deficiency/ies found and prompt the applicant to apply again through the eServices Portal.

### **IV. Payment of Fees**

1. Payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. Always indicate the Reference Number reflected in the OP. Clients will be informed of other available channels of payment through an FDA issuance.
2. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. This also means that the application will not proceed to the next step of the process.
4. Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, email will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.s

### **V. Evaluation**

1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.

2. The action on the application shall be Approval or Disapproval as provided by Republic Act (RA) 11032 otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act.
3. Evaluation shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

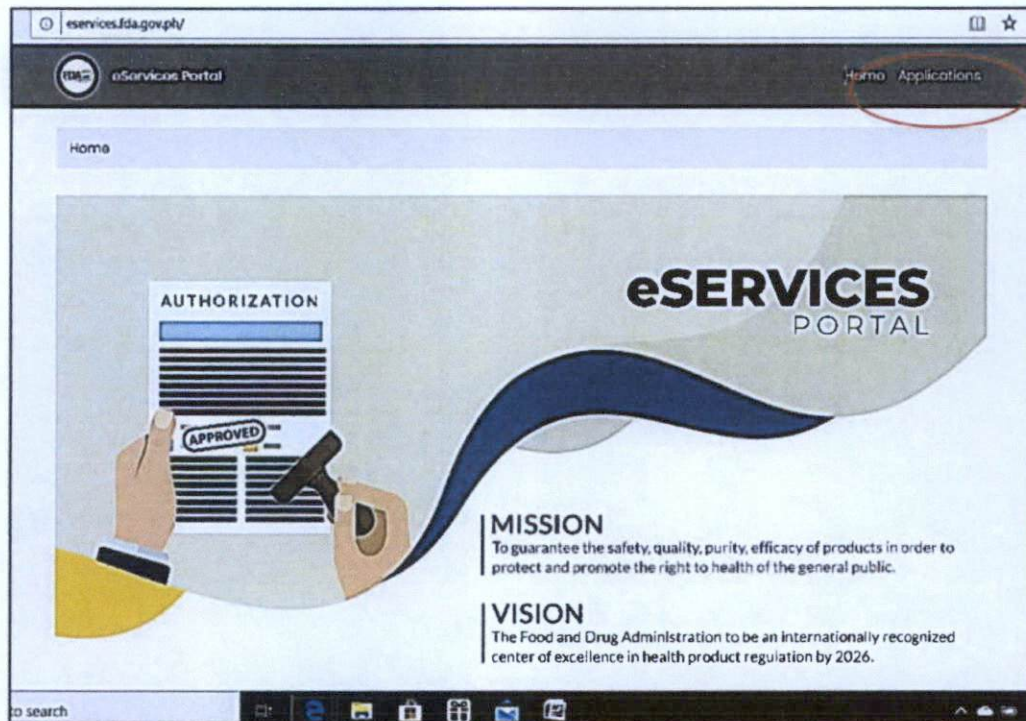


## ANNEX B

### Procedure on the Use of the FDA eServices Portal System for Compassionate Business Permit (CSP) New Application

#### A. New CSP Application on NAMED PATIENT USE

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click **"Applications"** found on the upper right corner of the landing dashboard.



2. Click on the **Compassionate Special Permit**.



3. Click on the **Named Patient Use** and **New Application**.

**Compassionate Special Permit**

**Application Status**  
Check the current status of your application

**Named Patient Use**  
Application for specific patient


**Institutional Use**  
Application for specific institution for their patient use

**Named Patient Use**

**New Application**  
Submission of new request to avail the access of an unregistered or investigational drug

4. Read carefully the **“Declaration and Undertaking”** before proceeding with the application process. Make sure to check the box found and click **“Start Application”**.




eServices Portal
Home Applications

Home / Applications / CSP / Named Patient Use / New application

## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

### Declaration & Undertaking

In compliance with the requirements as provided in the Administrative Order No. 2020-028, the following are the terms and conditions for the use of an issued CSP:

1. The subject product shall only be used in the treatment of the conditions specified in the permit.
2. The volume to be imported shall not exceed the allowed maximum number as stated in the permit.
3. The FDA shall not be held responsible for any damage or injury arising from the use of the drug product, and that the prescribing doctor or hospital shall accept the full responsibility.
4. In coordination with the licensed importer, the a) clinical report/s after the use of the product, b) reconciliation report, and c) other product details shall be submitted.
5. At any time deemed necessary by the FDA, the validity of the CSP may be revoked.
6. This one-time permit is valid for only one (1) year from the date of issue.

☐ I have read and accepted the terms and conditions stated on this form.  
In order to proceed with your application, you need to agree with the terms and conditions

Start Application

5. Fill-out all the information accurately. The e-mail address shall be official and the applicant shall make sure that it is within his/her scope.

Please take note that all the fields marked with asterisk (\*) are required to be filled-out.

All necessary information must be provided.

## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

### Applicant Information

\* First Name   
Middle Name   
\* Last Name   
\* Type of Applicant

### Contact Details

\* Email Address   
\* Mobile Number   
network code(09xx)  
Landline Number   
area code(02)

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## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

### Institution Information

\* Name of Institution or Hospital

### Address Details

\* Region   
\* Province   
\* City or Town   
\* Line Address   
Bldg No. / Lot No. / Home No. / Street / Subdivision / Barangay Address

### Contact Details

\* Email Address   
\* Landline Number   
area code(02)  
Mobile Number   
network code(09xx)

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## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

### Physician Information

\* First Name

First Name

Middle Name

Middle Name

\* Last Name

Last Name

\* Position

Position

\* PRC No.

PRC No.

\* Date of Birth

Please Select a Date

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## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

### Patient Information

\* First Name

First Name

Middle Name

Middle Name

\* Last Name

Last Name

\* Age

Age

\* Diagnosis

Diagnosis

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6. Select from the drop-down button the answer for "Is the Product registered in the Country of Origin?"

**New Application**

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 **Product Information**

7 Importer Information


8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

**Product Information**

\* Is the Product Registered in the Country Origin

Please Select 

This is a required field

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If the applicant chooses YES, he/she needs to identify the following;

- Generic Name of the product
- Dosage strength and form
- Packaging/Availability
- Approved Indication
- Total No./Volume to be Imported

**New Application**

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 **Product Information**

7 Importer Information


8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

**Product Information**

\* Is the Product Registered in the Country Origin

Yes 

\* Generic Name

Generic Name

Brand Name (if any)

Brand Name (if any)

\* Dosage Strength and Form

Dosage Strength and Form

\* Packaging/Availability

Packaging/Availability

\* Approved Indication

Approved Indication

\* Total No./Volume to be Imported

Total No./Volume to be Imported

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If the applicant chooses **NO, WITH ONGOING PHASE 3 CLINICAL TRIAL**, he/she needs to identify the following:

- a. Investigational Drug or Code
- b. Study Name
- c. Study Sponsor Number
- d. Study Registration Number
- e. Study Registration Country
- f. Dosage Strength and Form
- g. Packaging/Availability
- h. Target Indication
- i. Total No./Volume to be Imported

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

Product Information

\* Is the Product Registered in the Country Origin  
No. with ongoing Phase 3 Clinical Trial

\* Investigational Drug or Code  
Investigational Drug or Code

\* Study Name  
Study Name

\* Study Sponsor Number  
Study Sponsor Number

\* Study Registration Number  
Study Registration Number

\* Study Registration Country  
Please Select

\* Dosage Strength and Form  
Dosage Strength and Form

\* Packaging/Availability  
Packaging/Availability

\* Target Indication  
Target Indication

\* Total No./Volume to be Imported  
Total No./Volume to be Imported

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## 7. Fill-out the **Importer Information**.

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

Importer Information

\* License to Operate  
License to Operate  
license to Operate is a required field

\* Date of Validity  
Please Select a Date

\* Importing Company  
Importing Company

\* Company Address  
Company Address

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8. Fill-out the **Foreign Supplier** tab and choose from the drop-down button of the **Country of Source**.

**New Application**

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

**8 Foreign Supplier**

9 Documentary Requirements

10 Self-Assessment Review

**Foreign Supplier**

\* Name of Foreign Supplier

\* Country of Source

Country of Source is a required field

9. Upload all the necessary documents.

**New Application**

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

**9 Documentary Requirements**

10 Self-Assessment Review

**Documentary Requirements**

\* Curriculum Vitae of the Prescribing Doctor

\* Medical Abstract of Patient

\* Medical Prescription



10. Applicant may review if all the details are correct in the “Self-Assessment Review”.

### New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Physician Information

5 Patient Information

6 Product Information

7 Importer Information

8 Foreign Supplier

9 Documentary Requirements

10 Self-Assessment Review

#### Self-Assessment Review

##### Applicant Information

\* First Name

JOHN

Middle Name

DOE

\* Last Name

LOR

\* Type of Applicant

Institution

##### Contact Details

\* Email Address

joacosta@fda.gov.ph

\* Mobile Number

+ 09454885998

network code(09XX)

Landline Number

+ 02XXXXXXX

area code(02)

##### Institution Information

11. Once reviewed, the Applicant shall confirm the correctness of data given and click on “Confirm” to submit the application.

☐ I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

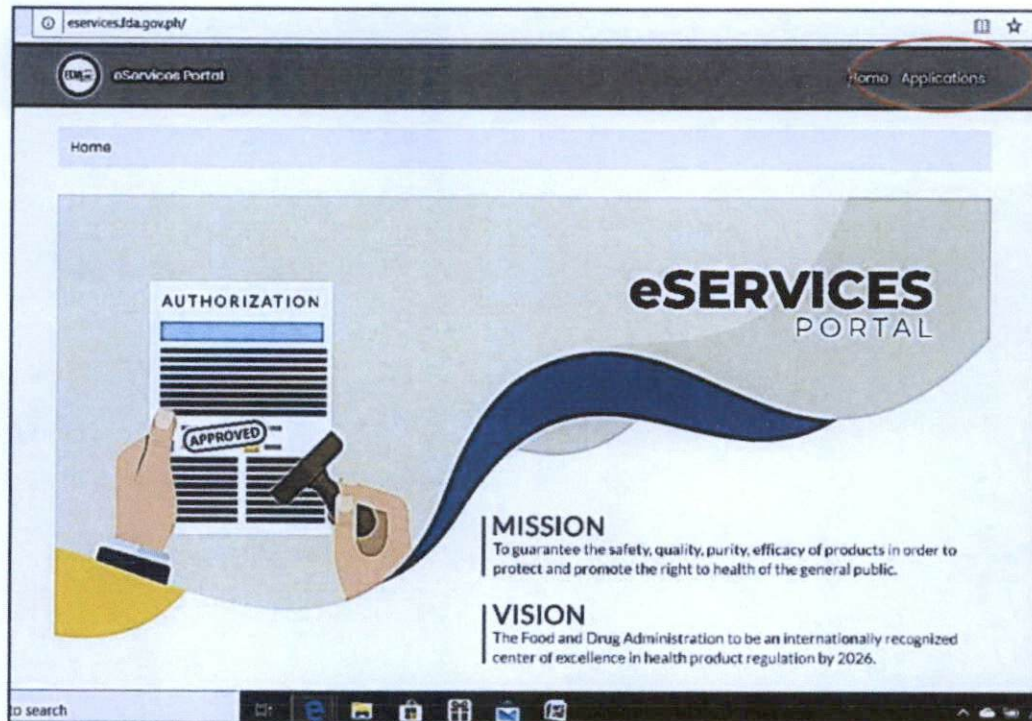
I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

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Confirm

## B. New Application on INSTITUTIONAL USE

1. Access the online portal through [eservices.fda.gov.ph/](https://eservices.fda.gov.ph/) and click “Applications” found on the upper right corner of the landing dashboard.




2. Click on the **Compassionate Special Permit**.






3. Click on the **Institutional Use** and New Application.

 eServices Portal


Home Applications

Home / Applications / CSP


Compassionate Special Permit




**Application Status**  
Check the current status of your application



**Named Patient Use**  
Application for specific patient




**Institutional Use**  
Application for specific institution for their patient use

 eServices Portal

Home Applications

Home / Applications / CSP / Institution

Institutional Use



**New Application**  
Submission of new request to avail the access of an unregistered or investigational drug

4. Read carefully the **“Declaration and Undertaking”** before proceeding with the application process. Make sure to check the box found and click **“Start Application”**.

## New Application

### 1 Declaration & Undertaking

### Declaration & Undertaking

In compliance with the requirements as provided in the Administrative Order No. 2020-028, the following are the terms and conditions for the use of an issued CSP:

1. The subject product shall only be used in the treatment of the conditions specified in the permit.
2. The volume to be imported shall not exceed the allowed maximum number as stated in the permit.
3. The FDA shall not be held responsible for any damage or injury arising from the use of the drug product, and that the prescribing doctor or hospital shall accept the full responsibility.
4. In coordination with the licensed importer, the a) clinical report/s after the use of the product, b) reconciliation report, and c) other product details shall be submitted.
5. At any time deemed necessary by the FDA, the validity of the CSP may be revoked.
6. This one-time permit is valid for only one (1) year from the date of issue.

### 2 Applicant Information

### 3 Institution Information

### 4 Product Information

### 5 Importer Information

### 6 Foreign Supplier

### 7 Documentary Requirements

### 8 Self-Assessment Review

☒ I have read and accepted the terms and conditions stated on this form. In order to proceed with your application, you need to agree with the terms and conditions

[Start Application](#)

5. Fill-out all the information accurately. The e-mail address shall be official and the applicant shall make sure that it is within his/her scope.

Please take note that all the fields marked with asterisk (\*) are required to be filled-out.

All necessary information must be provided.

## New Application

### 1 Declaration & Undertaking

### 2 Applicant Information

### 3 Institution Information

### 4 Product Information

### 5 Importer Information

### 6 Foreign Supplier

### 7 Documentary Requirements

### 8 Self-Assessment Review

### Applicant Information

\* First Name

Middle Name

\* Last Name

\* Position

### Contact Details

\* Email Address

\* Mobile Number  + 09XXXXXXXXX  
network code(09XX)

Landline Number  + 02XXXXXXXXX  
area code(02)

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## New Application

1 Declaration & Undertaking  
2 Applicant Information  
**3 Institution Information**  
4 Product Information  
5 Importer Information  
6 Foreign Supplier  
7 Documentary Requirements  
8 Self-Assessment Review

### Institution Information

\* Name of Institution or Hospital

### Address Details

\* Region

\* Province

\* City or Town

\* Line Address

Blk No. / Lot No. / Home No. / Street / Subdivision / Barangay Address

### Contact Details

\* Email Address

\* Landline Number

area code(02)

Mobile Number

network code(09XX)

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6. Select from the drop-down button the answer for *"Is the Product registered in the Country of Origin"*

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## New Application

1 Declaration & Undertaking  
2 Applicant Information  
3 Institution Information  
**4 Product Information**  
5 Importer Information  
6 Foreign Supplier  
7 Documentary Requirements  
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### Product Information

\* Is the Product Registered in the Country Origin

This is a required field

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If the applicant chooses **YES**, he/she needs to identify the following;

- a. Generic Name
- b. Dosage Strength and Form
- c. Packaging/Availability
- d. Approved Indication
- e. Total No./Volume to be Imported

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### New Application

<ol style="list-style-type: none"> <li>1 Declaration &amp; Undertaking</li> <li>2 Applicant Information</li> <li>3 Institution Information</li> <li>4 Product Information</li> <li>5 Importer Information</li> <li>6 Foreign Supplier</li> <li>7 Documentary Requirements</li> <li>8 Self-Assessment Review</li> </ol>	<p><b>Product Information</b></p> <p>* Is the Product Registered in the Country Origin <input type="text" value="Yes"/></p> <p>* Generic Name <input type="text" value="Generic Name"/></p> <p>Brand Name (if any) <input type="text" value="Brand Name (if any)"/></p> <p>* Dosage Strength and Form <input type="text" value="Dosage Strength and Form"/></p> <p>* Packaging/Availability <input type="text" value="Packaging/Availability"/></p> <p>* Approved Indication <input type="text" value="Approved Indication"/></p> <p>* Total No./Volume to be imported <input type="text" value="Total No./Volume to be imported"/></p>
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If the applicant chooses **NO, WITH ONGOING PHASE 3 CLINICAL TRIAL**, he/she needs to identify the following;

- a. Investigational Drug or Code
- b. Study Name
- c. Study Sponsor Number
- d. Study Registration Number
- e. Study Registration Country
- f. Dosage Strength and Form
- g. Packaging/Availability
- h. Target Indication
- i. Total No./Volume to be Imported

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### New Application

<ol style="list-style-type: none"> <li>1 Declaration &amp; Undertaking</li> <li>2 Applicant Information</li> <li>3 Institution Information</li> <li>4 Product Information</li> <li>5 Importer Information</li> <li>6 Foreign Supplier</li> <li>7 Documentary Requirements</li> <li>8 Self-Assessment Review</li> </ol>	<p><b>Product Information</b></p> <p>* Is the Product Registered in the Country Origin <input type="text" value="No, with ongoing Phase 3 Clinical Trial"/></p> <p>* Investigational Drug or Code <input type="text" value="Investigational Drug or Code"/></p> <p>* Study Name <input type="text" value="Study Name"/></p> <p>* Study Sponsor Number <input type="text" value="Study Sponsor Number"/></p> <p>* Study Registration Number <input type="text" value="Study Registration Number"/></p> <p>* Study Registration Country <input type="text" value="Please Select"/></p> <p>* Dosage Strength and Form <input type="text" value="Dosage Strength and Form"/></p> <p>* Packaging/Availability <input type="text" value="Packaging/Availability"/></p> <p>* Target Indication <input type="text" value="Target Indication"/></p> <p>* Total No./Volume to be imported <input type="text" value="Total No./Volume to be imported"/></p>
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7. Fill-out the **Importer Information**.

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## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Product Information

5 Importer Information

6 Foreign Supplier

7 Documentary Requirements

8 Self-Assessment Review

### Importer Information

\* License to Operate

\* Date of Validity

\* Importing Company

\* Company Address

8. Fill-out the **Foreign Supplier** tab and choose from the drop-down button of the **Country of Source**.

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## New Application

1 Declaration & Undertaking

2 Applicant Information

3 Institution Information

4 Product Information

5 Importer Information

6 Foreign Supplier

7 Documentary Requirements

8 Self-Assessment Review

### Foreign Supplier

\* Name of Foreign Supplier

\* Country of Source

Country of Source is a required field

9. Upload the necessary documents such as;

- a. Rationale for the Volume Requested
- b. Proof of NRA Approval
- c. Distribution Agreement

Home / Applications / CSP / Institution / New application

### New Application

1 Declaration & Undertaking	* Rationale for the Volume Requested	Rationale for the Volume Requested	File Upload
2 Applicant Information	Proof of NRA Approval	Proof of NRA Approval	File Upload
3 Institution Information	Distribution Agreement	Distribution Agreement	File Upload
4 Product Information			
5 Importer Information			
6 Foreign Supplier			
7 Documentalory Requirements			
8 Self-Assessment Review			

Additional requirement for emergency use drug only

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10. Applicant may review if all the details are correct in the “Self-Assessment Review”.

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### New Application

1 Declaration & Undertaking	Self-Assessment Review
2 Applicant Information	Applicant Information
3 Institution Information	* First Name JANE
4 Product Information	Middle Name JOHN
5 Importer Information	* Last Name DOE
6 Foreign Supplier	* Position PHARMACIST
7 Documentalory Requirements	Contact Details
8 Self-Assessment Review	* Email Address jeacosta@fda.gov.ph
	* Mobile Number + 09454895988
	network code(09xx)
	Landline Number + 02XXXXXXX
	area code(02)



11. Once reviewed, the Applicant shall confirm the correctness of data given and click on **"Confirm"** to submit the application.

☐ I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

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## ANNEX C

### Procedure for Checking of Application Status in the eServices Portal System

1. Access the online portal through [eservices.fda.gov.ph](http://eservices.fda.gov.ph) and click “Applications” found on the upper right corner of the system.
2. Click on the Compassionate Business Permit and the “Application Status”.

Home / Applications / CSP

### Compassionate Special Permit



**Application Status**  
Check the current status of your application



**Named Patient Use**  
Application for specific patient



**Institutional Use**  
Application for specific institution for their patient use

3. Enter the Reference Number of the submitted application and click “Submit”. The Reference Number can be found on the Acknowledgement Receipt of the application sent to Applicants registered e-mail address.

Home / Applications / CSP / Status

### Application Status

1 Reference Number

2 Verification Code

3 Application Status

1 Enter the reference number indicated in your application.

\* Reference Number

e.g. FDA-2000000001234

4. A verification code shall be sent to the registered e-mail address in your application.
5. Enter the verification code to view the progress of your application.