

**Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization**

**Notice**

**File No.:** IT-13011(11)/1/2023-eoffice

**Date:** 01/01/2024

**Subject – Launching of National Single Window System (NSWS) Portal- reg.**

NSWS is established by the Central Government with the objective to build a genuine Single Window System which act as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business. The scope of NSWS includes all the approvals/licenses/registrations/clearances as applicable.

In this regard, Invest India through TCS has developed NSWS portal has been developed for CDSCO, which will be independent from the existing SUGAM portal or cdscomonline portal. Initially following three activities under the Medical Devices Rules, 2017 have been developed and will be made 'Live' on NSWS portal w.e.f. 01.01.2024:-

1. Application for grant of Certificate of Registration of a Notified Body-Form MD-01.
2. Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training-Form MD-12.
3. Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training -Form MD-16.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said three activities through NSWS portal only and the existing cdscomonline portal for the said activities will be disabled **w.e.f. 15.01.2024.**

The NSWS portal can be browsed through <https://www.nsws.gov.in> and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

**Encl.:** As above

  
**(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)**

To:

1. All the concerned stakeholders
2. CDSCO Website

# National Single Window System

User Guide:

How to apply for CDSCO Approval

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# How to view, add approval through Central KYA

Access over **612 Central Approvals** and **4197 State Approvals**

## Explore, Apply and Get all the approvals required to start your business in India

Central Approvals  **EXPLORE ALL**

Don't know which approvals are required? [Click Here & Know Your Approvals](#)

*"We are laying a red carpet for all global companies to come and establish their presence in India. Very few countries will offer the kind of opportunities India does today."*

Hon'ble Prime Minister Narendra Modi

Click on 'Know Your Approvals' on the NSWS homepage

Begin your journey through KYA which helps generate a list of Centre and State approvals that may be required to start your business operations in India. This list of approvals is for guidance purposes only.

Which one would you like to go with first?

**Central** **State**

**Continue with Central** **Back to Homepage**

You understand that the 'Know Your Approval' feature is completely dependent on the information provided by You and is only indicative in nature to identify a list of Approvals and Registrations that may be required for Your business. This list does not constitute a legal opinion or advice and should be used only for reference purposes. We recommend you to undertake your own independent analysis and your application falls under the respective Ministry/ Department's jurisdiction.

Click on 'Continue with Central' to open the central KYA



# How to view, add approval through Central KYA

Click on 'Business Activity Details'

Select "Healthcare" and Answer the questionnaire and find applicability of different approvals to you

Click here to read more information

Click on 'My Approvals' tab to view the list of added approvals

To save a draft of the KYA answers, users must be logged into NSWS

Click 'Submit to Know Your Approvals' to view the list of approvals

Click on 'Reset form' to remove all previous responses to the questions



# How to add identified approval to the Dashboard

उद्योग संवर्धन और आंतरिक व्यापार विभाग  
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE

INVEST INDIA  
INDIA'S GROWTH PARTNER

About FAQs Guide Contact ENG

National Single Window System

CENTRAL APPROVALS  
Issued by Ministries of Govt. of India

STATE APPROVALS  
Issued by States of Govt. of India

GOVERNMENT SCHEMES  
Avail the benefits by Govt. of India

LOGIN

My Approvals(4) Edit KYA

Based on the information provided by you in the previous step, below is the list of approvals identified. This list of approvals is for guidance purposes only and does not constitute legal and/or official advice.

CENTRAL APPROVALS (4)

- 1 Form CT-10 Application for grant of permission for bioavailability or bioequivalence study or for examination, test and analysis  
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 2 CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study  
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 3 MOH\_Permission to manufacture new active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study  
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare
- 4 MOH\_Licence to manufacture drugs for purposes of examination, test or analysis  
For Business Activity Details • Issued by Directorate General of Health Services • Ministry of Health and Family Welfare

To add the list of approvals on the Dashboard, log into NSWS

Add to Dashboard

Know State Approvals

Save PDF

Save the existing list of approvals in pdf format using 'Save PDF'

National Single Window System

Sign In

To access your dashboard and apply for approvals.

Email Address

Password

Sign In

Don't have an account? Sign Up Now

We have 28 Ministries 22 States

Ministry of Civil Aviation Government of India

Ministry of Labour and Employment Government of India

Ministry of Corporate Affairs Government of India

Ministry of Information and Broadcasting Government of India

Ministry of Communications Government of India

Ministry of Fisheries, Animal Husbandry, and Dairying Government of India

Ministry of Finance Government of India

Ministry of Education Government of India

Government of Andhra Pradesh

Government of Arunachal Pradesh

Government of Bihar

Government of Gujarat

Government of Karnataka

Government of Goa

Users will be redirected to the 'Sign In' Page

Existing users can 'Sign In' with their credentials

New users can create an account using 'Sign Up Now'

# How to login and apply for approval (New User)

**Sign Up**  
We're so happy you're here, let's start by signing up.

Full Name\*  
Mukul Kumar

Email\*  
mukul123@gmail.com [Verify](#)

Mobile Number\*  
+91 9999999999 [Verify](#)

Set Password\*  
.....

**Sign Up Now**

By creating an account, I accept the Terms & Conditions and Privacy Policy

Have an account? [Sign In](#)

**We have**  
28 Ministries and 22 States

New users can create their login credentials. Add their Email ID & Phone Number and verify both of them

Click on 'Sign Up Now'

**Welcome**  
Mukul Kumar!  
You have been successfully registered on NSWS

2/4

**Setup your profile**  
Select your legal entity type

INCORPORATED COMPANY  
Select if you have a CIN

LIMITED LIABILITY PARTNERSHIP  
Select if you have an LLPIN

SOLE PROPRIETOR

OTHERS

NONE OF THESE, I'M PLANNING TO REGISTER A NEW ENTITY

NONE OF THESE, FDI IN INDIA

Enter CIN

**NEXT**

Select the applicable option

Enter the CIN / LLPIN / Business Name and click on 'Next'



# How to fill the application form

ERNST AND YOUNG INDIA PRIVATE LIMITED  
Incorporated on - 24/07/2002 CIN - U74140DL2002PTC116314

My Dashboard My Documents Members Profile

**My Dashboard**  
Manage and track the status of your application

Central Approvals in List (2 approvals)

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS + New Application	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	Subjective*	Apply Now
MDH_Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device	-	Mukul Kumar	Ministry of Health and Family Welfare	Not Applied	₹ 25000	Apply Now

Go Back

**Fill Application Form**  
Submit all the mandatory details(\*) in the application form to apply

FILL FORM REVIEW FORM MAKE PAYMENT

**FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS**

Part A  
FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...

Pre Registration Form

Applicant Address Details

Test or Analysis Site

Foreign Manufacturer details



# How to fill the application form

National Single Window System

 CENTRAL APPROVALS  
Issued by Ministries of Govt. of India
 

 STATE APPROVALS  
Issued by States of Govt. of India
 

 GOVERNMENT SCHEMES  
Avail the benefits by Govt. of India
 

 MY DASHBOARD

## Pre Registration Form

Select Department \* Biological - Blood Products

CDSO Applicable zone/HQ \* ▼

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. \*

## Applicant Address Details

Name of the Applicant \* Mukul

City \*

## Product Details

For each strength make new section application

Type of Drug \* 
 Bulk Drug  Finished Formulation
 
Name of Drug/Formulation \*

Class of Drug \* Select ▼

Quantity

Quantity  
Unit \*  
Select ▼

+ Add Section

## Product Details 2

For each strength make new section application

Type of Drug \* 
 Bulk Drug  Finished Formulation
 
Name of Drug/Formulation \*

Class of Drug \*



# How to fill the application form

## BA/BE Study Details

### Comparator Drug Details

Comparator Drug Name \*

Name of Company

Name of Country \* Select

+ Add Group ←

This button will create a duplicate group for the selected group

### Comparator Drug Details 2 🗑️

Comparator Drug Name \*

Name of Company

Name of Country \* Select

## Foreign Manufacturer details

Name of the Foreign Manufacturer \*

Country \* Select

Address Line 1 \*

Address Line 2 \*

State/Province/Region \*

City \*

Zip/Postal code \*

Fax No \* ❗

Landline No \* ❗

Please include Country Code - State Code - Landline Number

Click on '(i)' icon to read Additional Information



# How to fill the application form

<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
An explanation about whom to contact for trial related queries, ri	The anticipated prorated payment, if any, to the Subject for partic
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Subject's responsibilities on participation in the trial	Statement that participation is voluntary, that the Subject can wit
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
PI's undertaking	International prescribing information
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
Justification ⓘ	
<input type="text"/>	

Use this button to save the progress of the filled up application

Part C
Checklist-F12-BIO-BP-FFBD
Move to the Checklist form for uploading the required documents

## Checklist

**1. Name of Applicant (Applicant Details)**

Name of Applicant (Applicant Details) \*

Supported files are PDF

Name of Applicant (Applicant Details) - Remarks \*

**2. Drug Details**

Drug Details \*

Supported files are PDF

Drug Details - Remarks \*

This button indicates that the user needs to Download a format, fill it up and upload the same on that particular field



# How to fill the application form

The screenshot shows the 'National Single Window System' interface. At the top, there are navigation tabs for 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. The main content area contains two identical sections for file uploads and remarks. Each section starts with a text block: 'An undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons'. Below this is a 'Browse File' button, followed by 'Supported files are PDF' and a link to 'dummy.pdf'. A 'Remarks' field is also present, with the text 'Document' entered. At the bottom of the form, there is a 'Review & Submit' button. A callout box with an arrow points to this button, containing the text: 'Once filled, click on Review and Submit'.

The screenshot shows the 'National Single Window System' interface for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. The top navigation bar is the same as in the previous screenshot. Below the navigation bar, there is a progress indicator with three steps: 'FILL FORM', 'REVIEW FORM', and 'MAKE PAYMENT'. The main content area is titled 'Part A' and 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, ...'. It shows a table for 'Pre Registration Form' with the following data:

Select Department	Biological - Blood Products
Purpose of Application	For Examination, Test or Analysis
CDSO Applicable zone/HQ	CDSO HQ
I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.	Accepted

Below the table, there is a section for 'Applicant Address Details'. To the right of the table, there is an 'Application Fee' of ₹5,000. A callout box with an arrow points to this fee, containing the text: 'Applicable fee will be visible here'. At the bottom of the form, there is a checkbox with the text: 'I have reviewed all the information provided by me and confirm that it is correct to the best of my knowledge.' Below this, there are two buttons: 'Pay & Submit' and 'Back to edit details'. A callout box with an arrow points to the 'Pay & Submit' button, containing the text: 'Review the application and click here for final submission'.



# How to fill the application form

**Review your application**  
Please carefully review the application before submission

**FORM-12- APPLICATION**

**Part A**  
FORM-12- APPLICATION TO IMPORT DRUGS

**Disclaimer**

By proceeding with the payment, You acknowledge that the payment is being made directly to the concerned Ministry towards application fees (if applicable) or any other fees that may be charged by them. NSWS shall not be obligated to pay or refund any monies to You in any circumstance and is also not liable to facilitate refund of any payment made by You to the concerned Ministry. You may reach out directly to the concerned Ministry/ State in case of any discrepancies.

I have read and accept.

**Pay & Submit**      **Cancel**

Click on the checkbox and then "Pay & Submit" button

training.pfms.gov.in/Bharatkosh/NTRP/Home/Confirmation

Pay the amount using the Bharatkosh portal

Non-Tax Receipt Portal

1      2      3      4

Payment Purpose      Depositor's Details      Confirm Info      Pay

**Payment Mode Online**

Depositor's Details						
Name	MUKUL KUMAR					
Address 1	DS50	Address 2				
City	WEST DELHI	District				
State	DELHI	Country	INDIA			
Pincode/Zipcode	110063	Email	mukul682937@gmail.com			
Mobile No. (+91)	7042517135					
TAN		TIN				

Purpose Details						
Sr. No.	Ministry	P&O Name	DDO Name	Purpose and Payment Type	Payment Period / Frequency	Amount (in INR)
1	HEALTH and FAMILY WELFARE	PAO(DGHS), New Delhi(020946)	Section Officer, CDSCO (HQ), New Delhi(203700)	Import and Registration,	One Time	5000
				INR five thousand only		Total:5000

← Back
Confirm →

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# How to fill the application form

3 easy steps to add Digital Signature

- Step 1 Download and run emBridge Application. [Download](#)
- Step 2 Insert your crypto-token Pen Drive into system
- Step 3 Fill details here to add digital signature

After payment, user will be redirected to NSWS portal where the user has to Digitally Sign the application

Document for sign: MOH\_Certificate for Registration

This is the document containing the responses of the investor in the application with their DSC. Also known as Legal Form

Provider: Microsoft Windows Store

Certificate: Class 3 Individual Test

Token Password: \*\*\*\*

Sign & Submit

Submitted Successfully

Your application for 'MOH\_Certificate for Registration of Notified Body' has been submitted successfully to the respective Ministry. Please check the status from your dashboard.

Application ID: SW/MD/MD-1/2023/00000300

Application ID	SW/MD/MD-1/2023/00000300
Paid Amount	₹25000
Transaction ID	T1687768381684A53704L3335P22603
Date	26 Jun 2023 02:03 pm
Email	muskan3675@gmail.com

Done

This screen confirms the submission of application



# How to fill the application form

My Dashboard

Manage and track the status of your application

1 My Central Approvals

0 My State Approvals

Central Approvals in List (1 approvals)

Approval Name	Applied on	Last Submitted By	Assigned to	Application Status	Application fees	Action
MOH_Cert				Submitted	₹ 25000	Upload Doc.

Once submitted, user can track the 'Application Status' from here

In case the user wants to submit any additional document. They can click here

5. Additional Documents :

Document Type \*

1.2 Organization profile of notified body including organogram, busin...

Upload document \*

other Browse File

Supported files are PDF

Remarks \*

+ Add Section

Review & Submit Save as Draft

Upload the documents, add the information

Click on review and submit, and verify the application again using DSC as shown earlier



# How to view the application form (Legal Form)

The screenshot shows the National Single Window System dashboard. At the top, there are navigation links for 'About', 'FAQs', 'Guide', and 'Contact', along with a language selector set to 'ENG'. Below this, there are sections for 'National Single Window System', 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. A 'MY DASHBOARD' button is visible in the top right. The main content area shows an application for 'MOH\_Certi' with a status of 'Submitted'. A callout box with a yellow arrow points to the 'Download Digitally Signed Application' button. To the right, there are details about the application: 'Applied on 26/06/2023 | 2:18 pm', 'App ID SW/MD/MD-1/2023/00000300', and the 'Directorate General of Health Services, Ministry of Health and Family Welfare'. Below the application details, there are tabs for 'Form 1', 'Form 2', 'Document', and 'Payment'. The 'Form 1' tab is active, showing the title 'Form 1 - MD-1 Application for grant of Certificate of Registration of a Notified Body' and a section for '1. Form Type'. On the right side of the dashboard, there is a 'Processing Details' section showing two 'Submitted' events on 26 Jun 2023.

In Case the user wishes to see the Legal form they can do so by clicking on this button

The screenshot shows the 'Form MD-1' application form. The form title is 'Form MD-1 (See sub-rule (5) of rule 13) APPLICATION FOR ISSUE OF CERTIFICATE OF REGISTRATION OF NOTIFIED BODY'. The form contains the following fields:

- 1. Name Of Applicant : -
- 2. Nature and Constitution of Body : Proprietorship
- 3. Corporate/Registered Office Address : KRISHNA NAGAR , North Delhi, Delhi, 110051 (India), -, 5756765
- 4. Details of accreditation :
  - Issued by : NABCB
  - Issued On : 06/01/2023
  - Valid Upto : 06/28/2023
- 5. Standard for which notified body has been accredited under rule 13 : ISO 13485
- 6. Payment Fees Details : Refer details in Payment Receipt.
- 7. Documents enclosed as specified in the Part 1 of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.

At the bottom of the form, there is a declaration: 'I/We undertake to comply with the provisions of the Drug and Cosmetic Act, 1940(23 of 1940) and the Medical Device Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time'. The form also includes fields for 'Place : delhi', 'Date : 26/06/2023', 'Name: Shaik Gajula', and 'Designation: owner'. A signature line is present at the bottom right: 'Signature of designated person in India :'. A callout box on the left side of the form states: 'The legal form can be previewed/downloaded'.



# Checklist Activation

[← Go Back](#)

## Fill Application Form

User will be presented with multiple tabs containing different checklists. Only one Checklist will be enabled for the investor to fill up, based on their Responses in the Pre Registration Form

Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1  
Form CT-12 - Application for grant of permission to manufacture formulation of un...

**Pre Registration form**

Select Department \*  
Select

Purpose of the application: \*  
Select

Location for processing of application \*  
Select

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. \*

National Single Window System

CENTRAL APPROVALS  
Issued by Ministries of Govt. of India

STATE APPROVALS  
Issued by States of Govt. of India

GOVERNMENT SCHEMES  
 Avail the benefits by Govt. of India

MY DASHBOARD

FILL FORM REVIEW FORM MAKE PAYMENT

[+ Expand All](#)

## Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or...

Form 1  
Form CT-12 - Application for grant of permission to manufacture formulation of un...

**Pre Registration form**

Select Department \*  
Biological (r-DNA incl Re combinant Blood Product)

Purpose of the application: \*  
Clinical Trial

Location for processing of application \*  
CDSCO Head Quarter

Applicable HQ \*  
HQ - Biological (r-DNA incl Re combinant Blood Product)

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division. \*

[Application Details](#)

Fill up the details on Pre registration Form. Click on the checkbox. Post this, Once the user clicks on Next Form at the bottom of the page, user will be presented with the checklist they have to fill.



# Checklist Activation

The screenshot displays the 'Form 9' checklist for 'CT12-BIO-rDNA-FFBD-Clinical Trial-Checklist'. The interface includes a top navigation bar with 'National Single Window System', 'CENTRAL APPROVALS', 'STATE APPROVALS', and 'GOVERNMENT SCHEMES'. A progress bar at the top indicates 'FILL FORM', 'REVIEW FORM', and 'MAKE PAYMENT'. The checklist is titled 'Form 9' and includes sections for '1. Covering Letter' and '2. Justification of Quantity'. A callout box points to the checklist items, stating: 'User will land on checklist enabled for them to fill up'. The '1. Covering Letter' section contains a dropdown for 'CDSO Checklist', a 'Browse File' button, and a text area for '1 Remarks' with the value 'NA'. The '2. Justification of Quantity' section contains a 'Select Document Type' dropdown and a 'Browse File' button.

The screenshot displays the 'Form 2' checklist for 'CT12-ND-FFBD-Test & Analysis-Checklist'. The interface is similar to the previous one, with a progress bar and navigation options. The checklist is titled 'Form 2' and includes sections for '1. Covering Letter of the firm' and '2. Self attested by Head of the institution proprietor or director of the company or firm'. A callout box points to the checklist items, stating: 'The checklists which are disabled for the user to fill in will appear as shown here. The user do not need to fill these up in order to submit their application'. The '1. Covering Letter of the firm' section contains a 'Select Document Type' dropdown with a red prohibition sign, a 'Browse File' button, and a text area for '1. Covering Letter of the firm - Remarks'. The '2. Self attested by Head of the institution proprietor or director of the company or firm' section contains a 'Select Document Type' dropdown and a 'Browse File' button.



## What are the technical Requirements for NSWS

### System Requirements for National Single Window Portal

- Windows OS (XP or higher)
- MAC OS (X 10.9 or higher with latest updates)
- **View/ Download Pdf:** Download the pdf reader to view and download the pdf files from the link: <https://get.adobe.com/reader/>
- Platform requires a minimum screen size of 976px wide , but using 1024px or higher is recommended
- **Digital Signature Certificate (DSC):** Latest version of emBridge software need to be installed in the system which acts a connecting link/driver between the NSWS and DSC

### Web browsers best suited for National Single Window System

- Google Chrome
- Mozilla Firefox
- Apple Safari

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### Have any further questions?

Please submit your queries and feedback on:

<https://www.nsws.gov.in/contact-us>

Email: [contactus-nsws@investindia.org.in](mailto:contactus-nsws@investindia.org.in)

Ph: 1800 102 5841

(Monday - Saturday, 9am - 6pm)

*Last Updated on 14 March 2023*



**DEPARTMENT FOR PROMOTION OF  
INDUSTRY AND INTERNAL TRADE**  
MINISTRY OF COMMERCE & INDUSTRY,  
GOVERNMENT OF INDIA

# **National Single Window System (NSWS)**

**CDSCO**

**Ministry User Guide**



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# 1 About This Manual

## 1.1 Purpose of this Manual

The purpose of this manual is to provide guidance to the CDSCO Ministry/Department users concerning:

- ❖ Services and Functionalities provided by National Single Window System (NSWS) for approval application processing.
- ❖ Step-by-step guide on how to evaluate approvals applications received through NSWS.

## 1.2 Organization of This Manual

This manual has been organized into the following parts:

- ❖ Overview of NSWS
- ❖ NSWS Ministry/Department User Services

## 1.3 Acronyms, Abbreviations, Definitions

Term /Abbreviation	Definition / Full Form
Approval	Approvals, as used in this document, refer to any regulatory or legal clearance to be obtained from the government by any investors, entrepreneurs, businessperson, or business entity before commencing any business activity in India, including but not limited to Approvals, Registrations, Licenses, Permits, Clearances, Certifications etc.
ICC	Investment Clearance Cell
Investment Clearance Cell	Cell setup under Invest India, DPIIT, to facilitate investors. Responsible for developing and maintaining NSWS
KYA	Know Your Approval
National Single Window System (NSWS)	The digital portal serving as the national single window system under the Investment Clearance Cell

## 2 Introduction to NSWS

### 2.1 Objective of NSWS

The Hon'ble Minister of Finance, Government of India, during the budget speech on 1st February 2020, announced the setting up of an Investment Clearance Cell (ICC). The proposed ICC has been developed as an online portal, named NSWS, which will act as a National Single Window System (NSWS) for investors, entrepreneurs, and businesses.

NSWS enables investors to identify, apply, track and obtain approvals needed before starting any business operations in India. This eliminates the need for investors to visit multiple IT platforms and authorities to gather information and obtain approvals from different stakeholders.

NSWS aims to fulfill the following objective:

- ❖ Establish a single window mechanism to integrate the services provided by various central government ministries, departments, and select state governments related to starting and operating any business activity.
- ❖ Provide a single window interface for procuring approvals required to commence a business in India.
- ❖ Provide efficient, convenient, transparent, and integrated electronic services to investors.
- ❖ Provide a uniform and seamless experience to the investor through a unified interface.

### 2.2 Scope of NSWS

NSWS covers Central and State approvals required by any investor, both foreign or domestic, before starting any business operations or activities in India, including but not limited to registrations, licenses, permits, NOCs and approvals. It provides a platform for any investor to identify, apply track and obtain final decision on their applications. The final authority of approving or rejecting applications resides with the respective authorities.

### 2.3 Salient Features and Advantages of NSWS

NSWS has been designed keeping the investor at the centre, and boasts of the following features:

- ❖ Provides a single unified interface to investors to identify, apply, track and obtain approvals.
- ❖ Helps investors identify applicable approvals depending on the specific business activities being planned and other investor-specific context.
- ❖ Provides an 'Approval Repository' where the investor can select and apply for any approvals, as needed.
- ❖ Reduces the need to fill in same information at multiple places through intelligent auto-population.
- ❖ Provides ability to track status of an application and raise reminders to authorities, as per agreed process, if any.

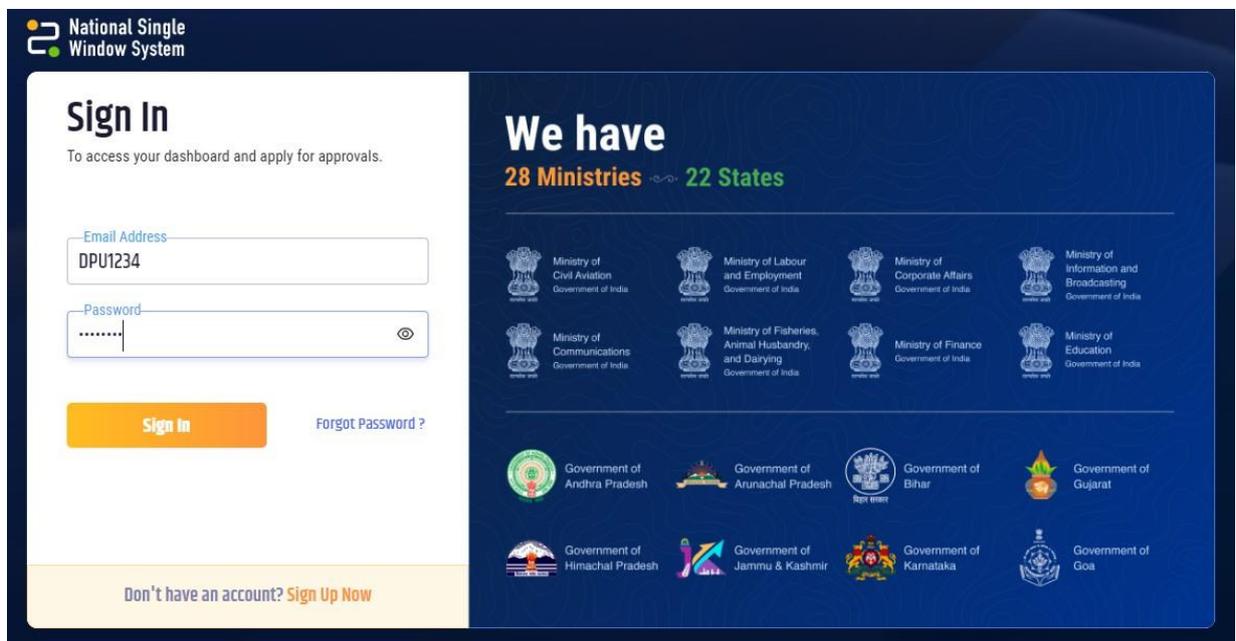
- ❖ Provides a unified document repository to where investors can upload and save their documents, and view and download documents issued to them by authorities.
- ❖ Provides an intuitive and easy to use communication module to respond to any clarifications or additional information requests raised by processing authority on submitted applications.
- ❖ Guides investor in situations where multiple forms or approvals need to be submitted in a specific sequence and timing.
- ❖ Provides a scheduler to arrange and conduct meetings online with concerned authorities, as per agreed process, if any.

### 3 Processing Applications on NSWS

#### 3.1 Ministry Dashboard Overview

##### 3.1.1 Ministry User Login

The authorised ministry officer can Login into the NSWS Ministry portal with the credentials available with them. The user can open the Ministry Login page from the Homepage of NSWS.



**The Ministry Dashboard on Login:** Upon logging-in the Ministry User will be redirected to the Dashboard. The Dashboard contains the count of Applications:

- ❖ **Assigned to me:** The applications that are pending for the specific logged in Ministry User to review.
- ❖ **New Application:** The fresh application that are applied by the investor and are yet to be reviewed.
- ❖ **Total Applications:** The total of the above stated Applications.

Ministry of Health and Family Welfare

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Mr. Sanjeev Kumar

### Applications

Assigned to Me(1) **New Applications(5)** Total Applications(8)

Filters

New request x View All Clear All

Approval Name	App Id	Organisation Name	Date of Submission	Pending With	Application Status
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	TO THE NEW PRIV...	13-06-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	pratheeksha	06-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	pratheeksha	03-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	FACEBOOK INDIA ...	01-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	sadasdasdad	01-02-2023	Mr. Sanj...	New Request

← PREV 1 NEXT → 10/ Page

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### 3.1.2 Viewing Applications

Upon opening Application tab, the system shall display status for the applied licenses. A fresh application will appear on top of the “Total Application” tab, or they can be opened by clicking on the “New Application” tab which will show all the new applications submitted by the users.

To open an application for scrutinization the user should click on the name of the approval

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### Applications

Assigned to Me(1) New Applications(5) **Total Applications(8)**

Filters

Approval Name	App Id	Organisation Name	Date of Submission	Pending With	Application Status
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	TO THE NEW PRIV...	13-06-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	pratheeksha	06-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	pratheeksha	03-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	FACEBOOK INDIA ...	01-02-2023	Mr. Sanj...	New Request
FORM-12-APPLICATION TO IMPORT...	SW/BID-BP/...	sadasdasdad	01-02-2023	Mr. Sanj...	New Request
Send to CT-13-APPLICATION FOR GRANT OF...	SW/SND/CT...	pratheeksha	23-12-2022	Mr. Sanj...	Pending
CT-10 APPLICATION FOR GRANT OF...	SW/FDC/CT...	-	25-07-2022	Dr. V. G...	Approved
CT-10 APPLICATION FOR GRANT OF...	SW/FDC/CT...	-	06-07-2022	Dr. V. G...	INPROCESS

← PREV 1 NEXT → 10/ Page

User can click on each section name to review the inputs filled by the investor

The screenshot displays the 'Total Applications' page in the National Single Window System. The left sidebar contains navigation options: Dashboard, Application (highlighted), Department & Licenses, My Details, Reports, and Ministry Guidance. The main content area shows a 'New Request' for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. The application details include App ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, and Applied on: 13-06-2023. A 'Download' button is visible. Below the application details, a horizontal menu lists sections: FORM-12-..., Checklist-..., Checklist-F12-..., Checklist-..., Document, Communic..., Payment, and Audit Log. A red dashed box highlights this menu. The main content area lists sections for review: Pre Registration Form, Applicant Address Details, Test or Analysis Site, Foreign Manufacturer details, Address Details, Product Details, and BA/BE Study Details. At the bottom, there is a checkbox for 'I accept that I have reviewed the form carefully.' and two buttons: '< Take Investor Action' and 'Take Internal Action >'. A vertical 'PROCESSING STATUS' indicator is on the right.

Ministry User can navigate the through a single form vertically.

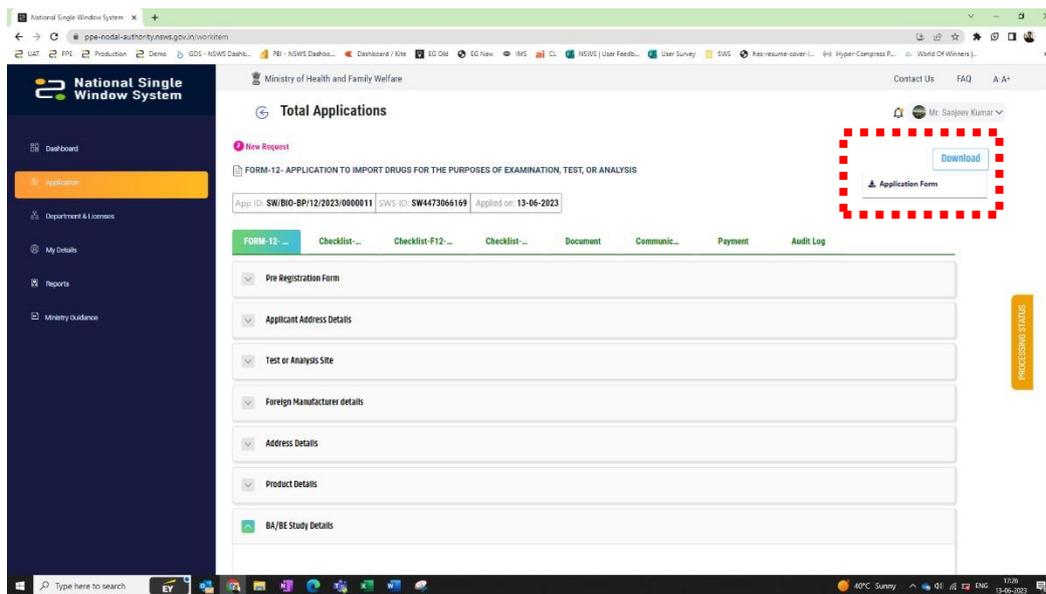
The screenshot shows a detailed view of the 'Pre Registration Form' within the National Single Window System. The left sidebar is the same as in the previous screenshot. The main content area shows the application details: App ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, Applied on: 13-06-2023. A horizontal menu lists sections: FORM-12-..., Checklist-..., Checklist-F12-..., Checklist-..., Document, Communic..., Payment, and Audit Log. A red dashed box highlights the 'FORM-12-...' section. The main content area displays the form fields: Select Department (Biological - Blood Products), Purpose of Application (For Examination, Test or Analysis), CDSCO Applicable zone/HQ (CDSCO HQ), CDSCO Applicable zone, and a declaration: 'I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.' with a status of 'Accepted'. Below the form, there are expandable sections for Applicant Address Details, Test or Analysis Site, Foreign Manufacturer details, and Address Details. A vertical 'PROCESSING STATUS' indicator is on the right.

### 3.1.3 Unique Application ID

For each application there will be a Unique Application ID which will be displayed on Investor as well as the Ministry portal throughout the entire scrutinization journey.

This close-up screenshot shows the 'New Request' section for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS'. A red dashed box highlights the application details: App ID: SW/BIO-BP/12/2023/0000011, SWS ID: SW4473066169, and Applied on: 13-06-2023.

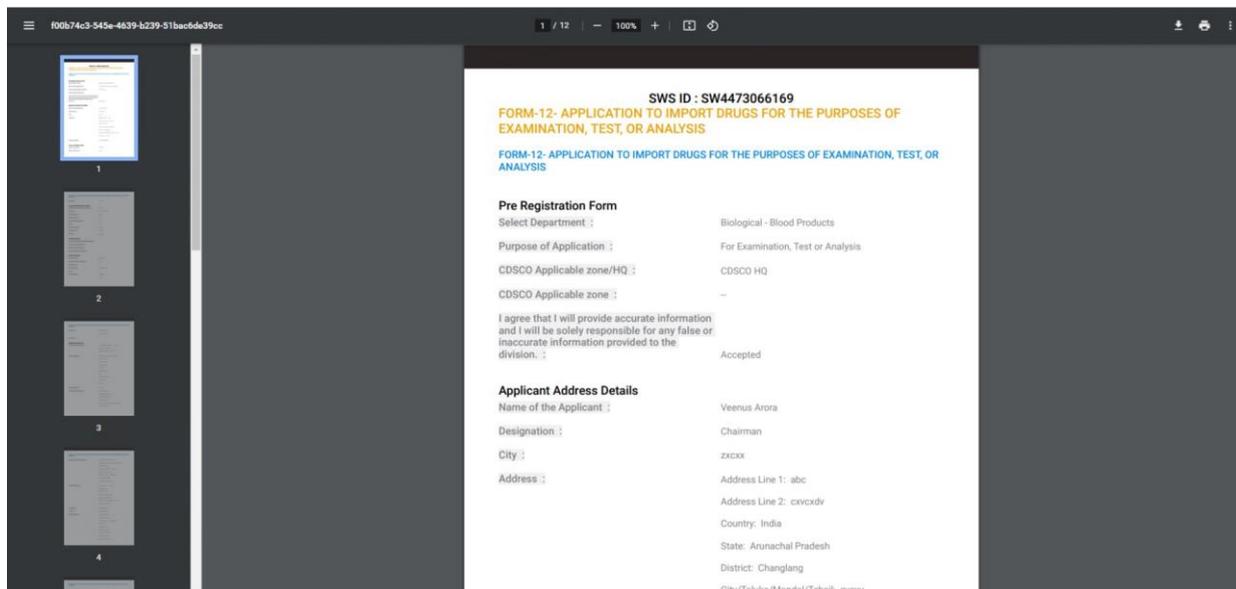
### 3.1.4 Download Application and Documents



An option to download the whole application submitted and the payment details is also provided to the Ministry User which will enable to easily visualize the Applicant’s Input by the Ministry User. The button to preview the application is given on the top right corner as shown in the above image.

This Document will include application inputs by the investor and the Payment Receipt Details

On downloading it the application can be previewed as shown below, the same can be downloaded / printed.



### 3.1.5 Viewing Documents

To view the documents submitted by the Investor, the Ministry User can click on the field and click on the Attached button beside such field. The Ministry User can click on the “Attached” button on the right side of each field to download the corresponding documents.

Upon clicking the attachment option, Ministry User will be presented with a split screen which will have two drop down lists having all the documents submitted by Investor in that particular Application in both of them. Thus, the Ministry user can view all the documents along with the option of comparing different documents.

### 3.1.6 Payment Status

User will be shown with the payment details of the submitted application by clicking on the Payment tab.

[FORM-12- ...](#)
[Checklist-...](#)
[Checklist-F12-...](#)
[Checklist-...](#)
[Document](#)
[Communic...](#)
[Payment](#)
[Audit Log](#)

**5000 INR**

Transaction ID T1686645848691A53144L4194P19114	Transaction Date Tue Jun 13 2023	Transaction Time 2:14:08 PM	<a href="#">Download Receipt</a>
---	-------------------------------------	--------------------------------	----------------------------------

The download invoice button will download a PDF having the payment receipt as shown below

### Payment Receipt

License	FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
SWS ID	SW4473066169
Transaction ID	T1686645848691A53144L4194P19114
Payment Reference Number	T1686645848691A53144L4194P19114
Bank Reference Number	358800
CIN Number	20370013062300050333
Payment Amount	5000
Currency Code	INR
Payment Type	CREDIT CARD
Payment Status	SUCCESS
Payment Date and Time	13/06/2023 14:14:09

### 3.1.7 Communication

This tab will show all the Scrutiny and Query raised between the Ministry and Investor. The terms will be explained in the guide.

**National Single Window System**

- Dashboard
- Applications
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

Ministry of Health and Family Welfare

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**Total Applications**

🔔   👤 Dr. Rubina

Download

Approved

FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

App ID: SW/BIO-BP/12/2023/000011   SWS ID: SW4473066169   Applied on: 14-06-2023

[FORM-12- ...](#)
[Checklist-...](#)
[Checklist-F12-...](#)
[Checklist-...](#)
[Document](#)
[Communic...](#)
[Payment](#)
[Audit Log](#)

Query History 01

Scrutiny History 01

Internal Communications

No Internal Communications made yet.

PROCESSING STATUS

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### 3.1.8 Audit Log

Audit log shows all the actions taken on the particular application taken the Ministry users and Investor

The screenshot shows the 'Audit Log' section of the National Single Window System. The application details for 'ABCD Ltd.' are displayed at the top, including SWS ID (SW4473066169), PAN (BBBCB1234G), CONTACT (9811809686), and EMAIL (veenun.ar@tcs.com). Below this is a table of audit log entries:

Date	Action	Remark	Action Taken by	Attachment
13-06-2023 14:14:08	Investor files application		Veenun	-
14-06-2023 09:25:53	Send to	Sic i have reviewed and it looks fine, sending it for your review and action	Mr. Sanjeev Kumar Gupta - Accountant	-
14-06-2023 10:54:34	Forward	File according to me. Please review	Mr. J. Suresh Kumar -Accountant	-
14-06-2023 12:04:19	Send to	Verified, please review	Mr. Sanjeev Kumar Gupta - Accountant	-
14-06-2023 12:14:21	Forward	verified, please review	Dr. Rubina Bose-Deputy Drugs Controller (India)	-

A 'Download' button is located at the top right of the log table. A vertical orange bar on the right side of the page indicates 'PROCESSING STATUS'.

### 3.2 Process for Application Review

Ministry User will be provided with two tabs as shown below

The screenshot shows the 'Application Review' section of the National Single Window System. The application details for 'FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS' are displayed at the top, including SWS ID (SW/BIO-BP/12/2023/0000011) and Applied on (13-06-2023). Below this is a list of application details:

- Pre Registration Form
- Applicant Address Details
- Test or Analysis Site
- Foreign Manufacturer details
- Address Details
- Product Details
- BA/BE Study Details

At the bottom, there is a checkbox for 'I accept that I have reviewed the form carefully.' and two buttons: 'Take Investor Action' and 'Take Internal Action'. A red dashed box highlights these two buttons. A vertical orange bar on the right side of the page indicates 'PROCESSING STATUS'.

#### 3.2.1 Take Internal Action

A ministry user can use this option when they have to communication regarding the application within the ministry.

Click on checkbox for "I accept that I have reviewed the form carefully" and then click on "Take Internal Action"

A ministry user can perform the following Internal Actions:

### 3.2.1.1 Seek Info

In case the ministry user wants to ask some specific information from any other user from the workflow, the application still remains with the same officer.

### 3.2.1.2 Forward to next level

In case the user wants to forward application for review to his immediate superior officer.

### 3.2.1.3 Send to

In case a ministry user wants to assign or reassign this application to any level user in the workflow. This will transfer the application to the assignee on which they can act upon.

The screenshot shows the 'Internal Action' menu with options: Forward to Next Level, Seek Info, Send To, Generate Draft Permission License, Notesheet, and Generate Draft Covering Letter. The 'Send To' option is selected. Below the menu is a 'Select User' dropdown menu with a list of users: Mr. Sanjeev Kumar Gupta -Accountant-NO-Level:1, Mr. Sanjeev Kumar Gupta -Accountant-NO-Level:3, Mr. Sanjeev Kumar Gupta -Accountant-DDA-Level:4, Dr. Rubina Bose-Deputy Drugs Controller (India)-DA-Level:5, and Dr. Rubina Bose-Deputy Drugs Controller (India)-LA-Level:6. At the bottom, there are buttons for 'Attachment' and 'Send', and a note: 'Note Supported files : PDF, JPEG, PNG, GIF. Maximum file size should be up to 100MB. Maximum 2000 characters are allowed for remarks.'

### 3.2.1.4 Pull Back and Reassign

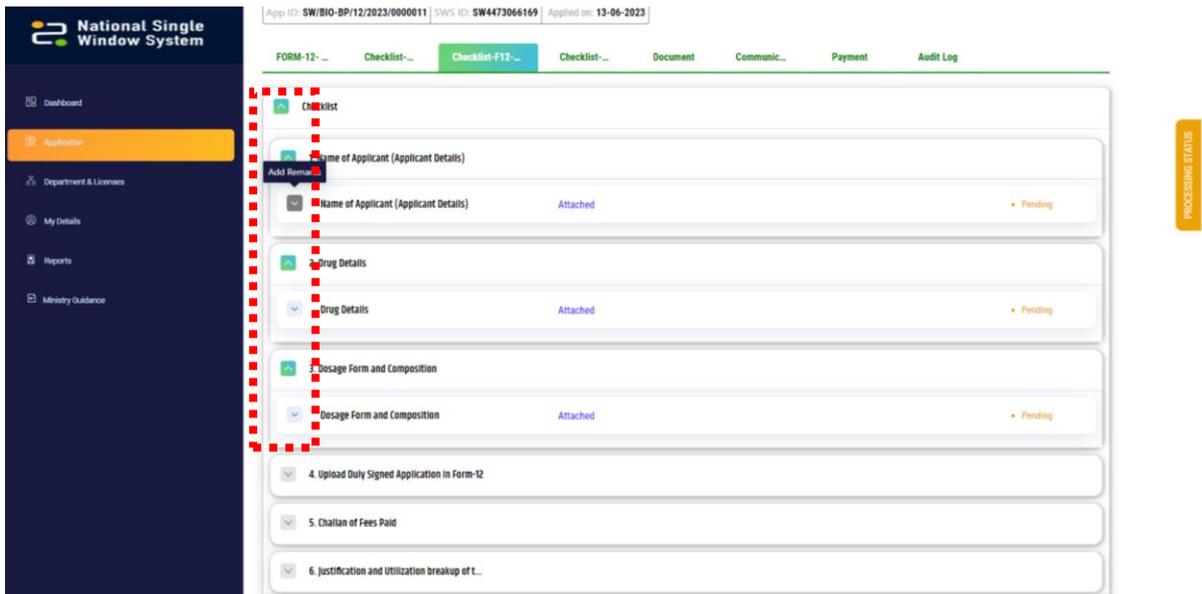
If the application is with a particular officer and they may not be able to process it (for example a leave or any official engagement), then the higher-level user to such officer can use this function to pull back the license from such user and reassign it to another officer.

The screenshot shows the 'Internal Action' menu with options: Seek Info, Pull Back and Reassign, Send To, and Notesheet. The 'Pull Back and Reassign' option is selected. Below the menu is a 'Select User' dropdown menu with the user: Mr. Sanjeev Kumar Gupta -Accountant-Level No:4-DDA. Below the dropdown is a text area containing the text: 'Pulling back and reassigning to D.D.A. (Deputy Deciding Authority)'. At the bottom right, there is a 'Reassign Request' button.

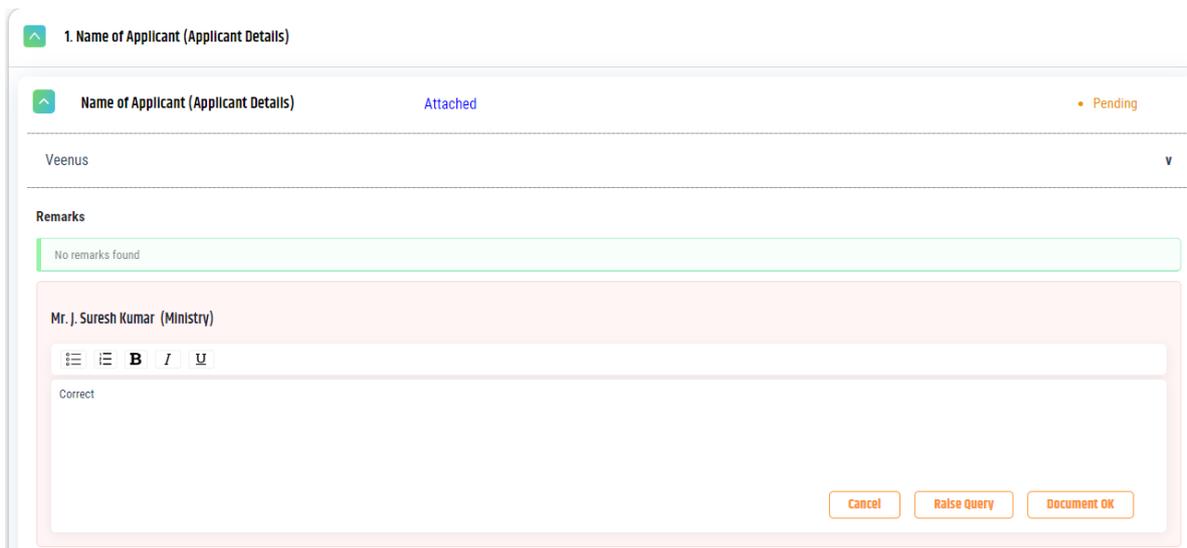
### 3.2.1.5 Review Checklist items

A ministry user has to review the checklist documents one by one in order to move the application to his higher-level officer. This process has to be done from Level 2 onwards till final level officer. There onwards, Each level officer has to complete this process.

User has to click on Checklist from the top vertical tab and open each item. Then click on the downward arrow beside each line item.

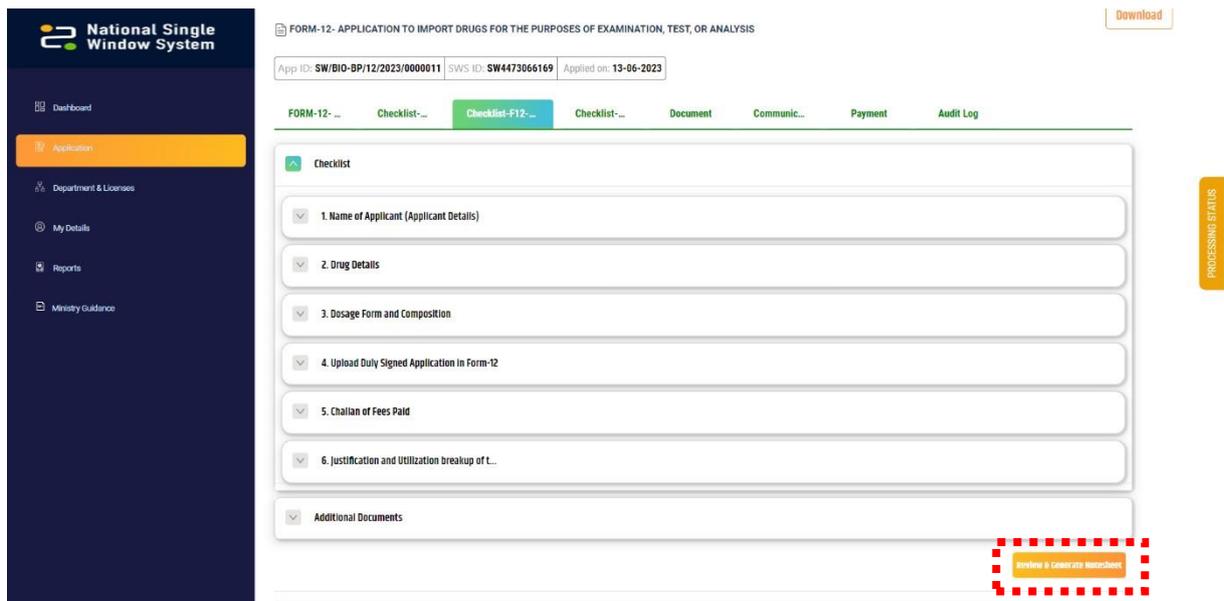


User can either raise query on the document which will be communicated to the investor, or they can provide their confirmation.

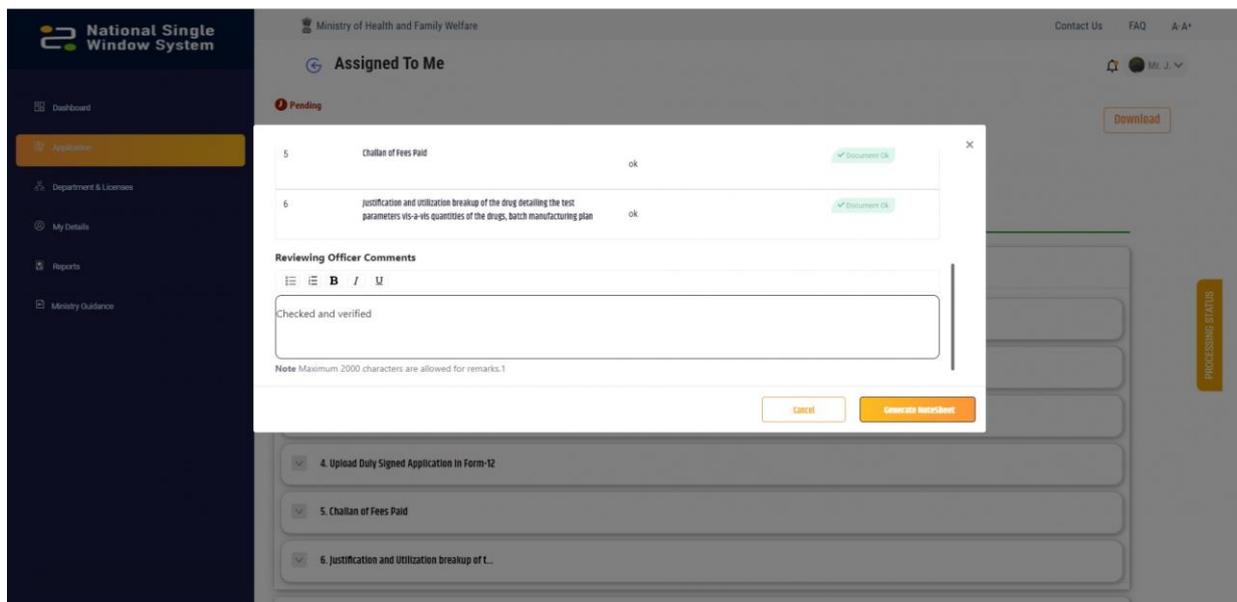


### 3.2.1.6 Generate Notesheet

Once completed with the review of all items in the checklist, user has to generate Notesheet from the showed option in order to move forward with the application

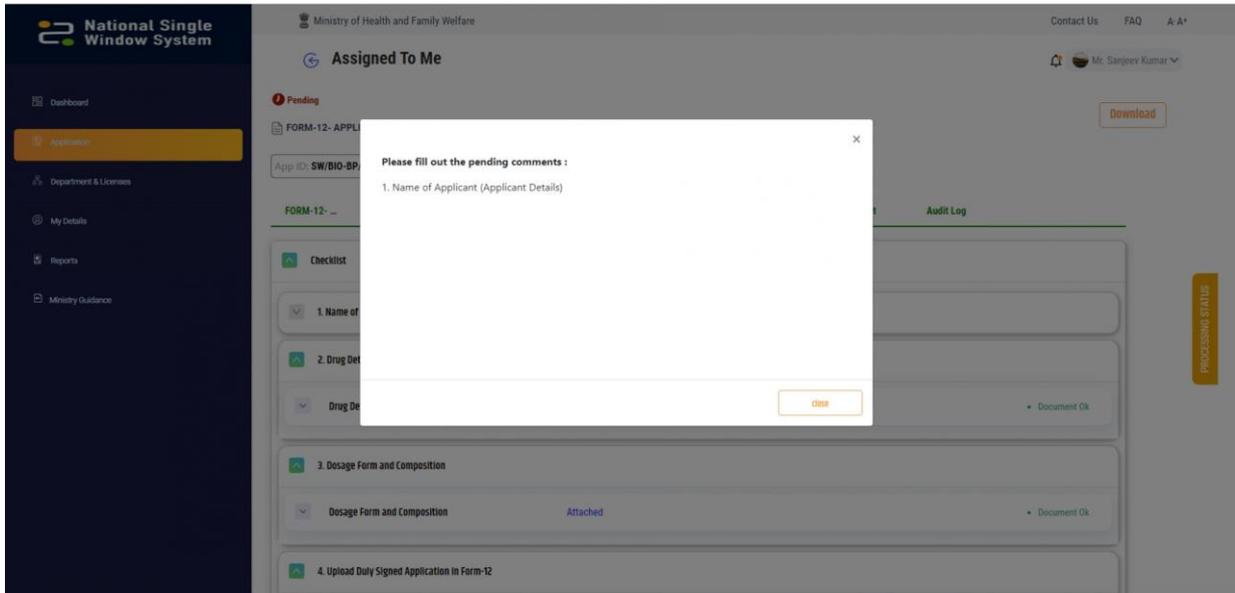


Provide confirmation through the comments and Generate Notesheet



A Ministry user has to complete “Review Checklist Items” and “Generate Notesheet” action as shown in 3.2.1.5 and 3.2.1.6, respectively, to forward the application

In case the user has missed a checklist item to verify, the system will communicate the same by showing this screen



### 3.2.1.7 Send Back

In case the ministry user wants to send it back to the last user for reviewing it again

**Internal Action** Go Back ✕

Forward to Next Level
Seek Info
Send Back
Send To

Generate Draft Permission License
Notesheet
Generate Draft Covering Letter

---

Dr. Rubina Bose-Deputy Drugs Controller (India)

B I U

Please review the address details section for site again.

Note Maximum 2000 characters are allowed for remarks.

Send ↗

### 3.2.1.8 View Notesheet

**Internal Action** Go Back ✕

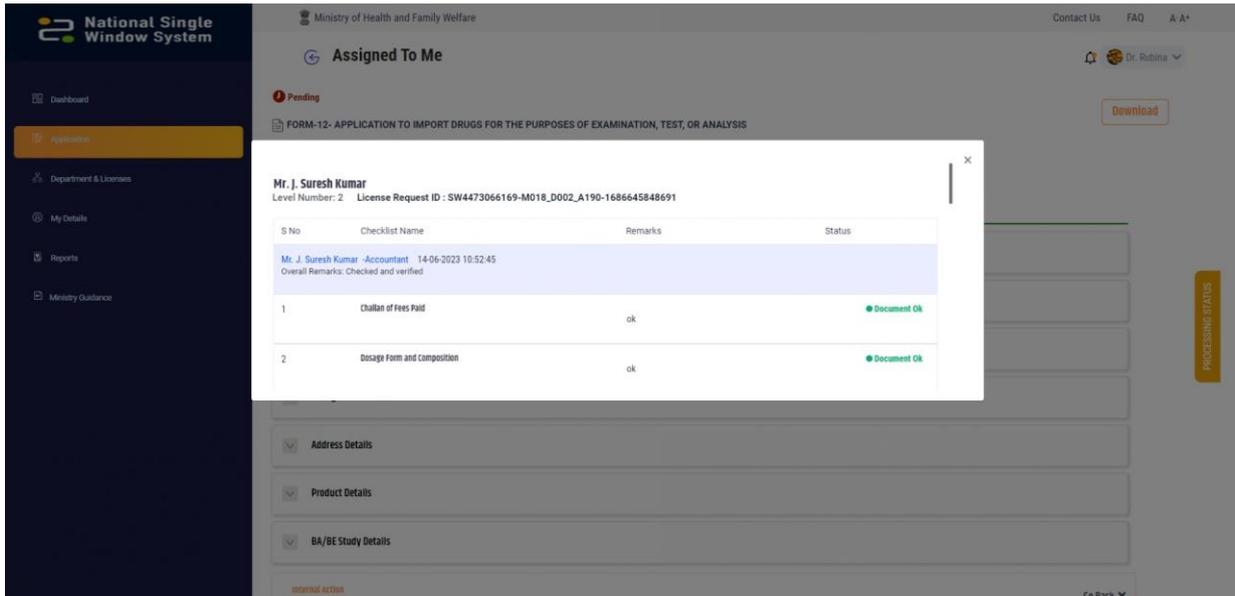
Seek Info
Send Back
Approve Application
Reject Application

Send To
Generate Permission/License
Notesheet
Generate Covering Letter

---

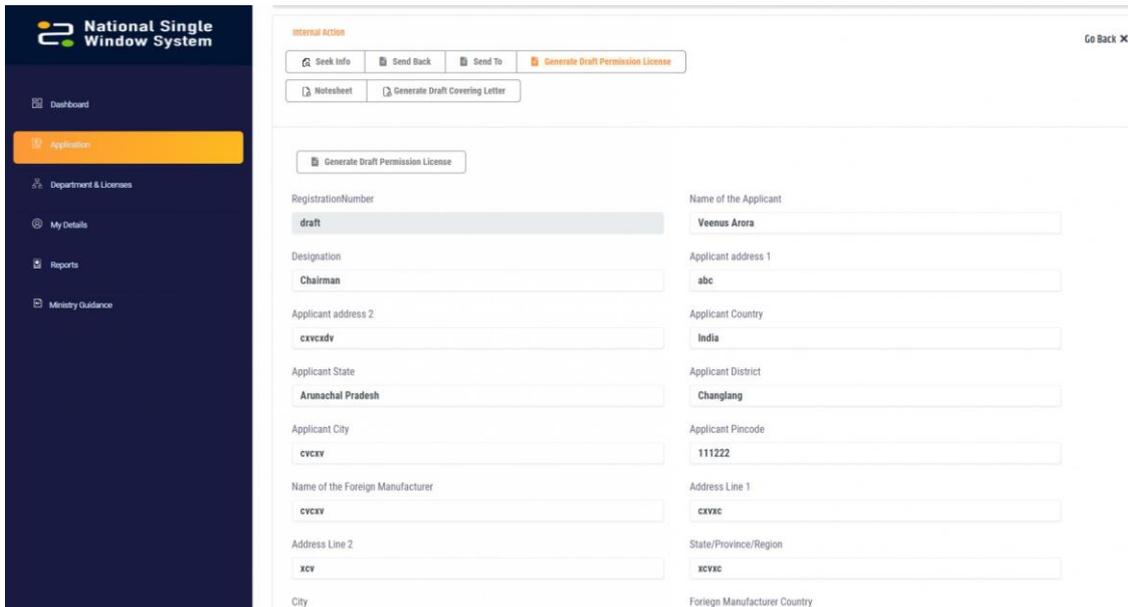
View NoteSheet

Notesheet captures actions taken by ministry users on checklist documents



### 3.2.1.9 Draft Permission License

- ❖ Ministry user can generate draft license using this option. User can click on the button and update or edit the required details.



- ❖ Click on Generate "Draft Permission License" as shown

**National Single Window System**

INTERNAL ACTION Go Back X

**Generate Draft Permission License**

Registration Number:

Name of the Applicant:

Designation:

Applicant address 1:

Applicant address 2:

Applicant Country:

Applicant State:

Applicant District:

Applicant City:

Applicant Pincode:

Name of the Foreign Manufacturer:

Address Line 1:

Address Line 2:

State/Province/Region:

❖ Click on “Generate Certificate” on bottom of the page

Zip/Postal code:

Landline No:

Fax No:

Name of the site:

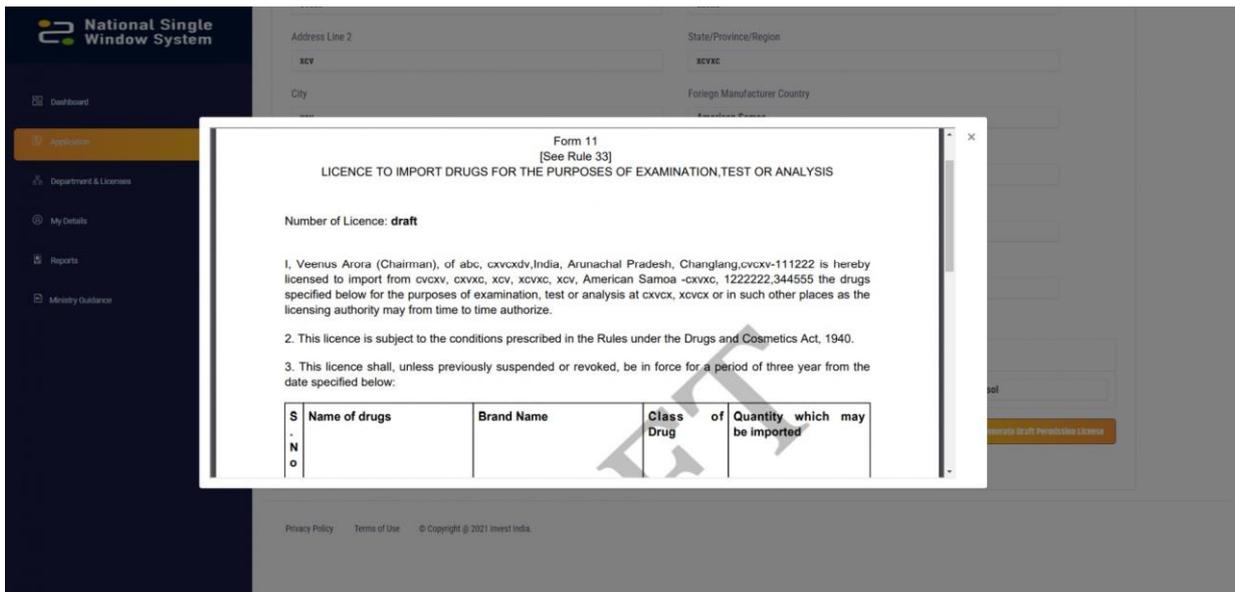
Address:

Select Department:

**Product Details**

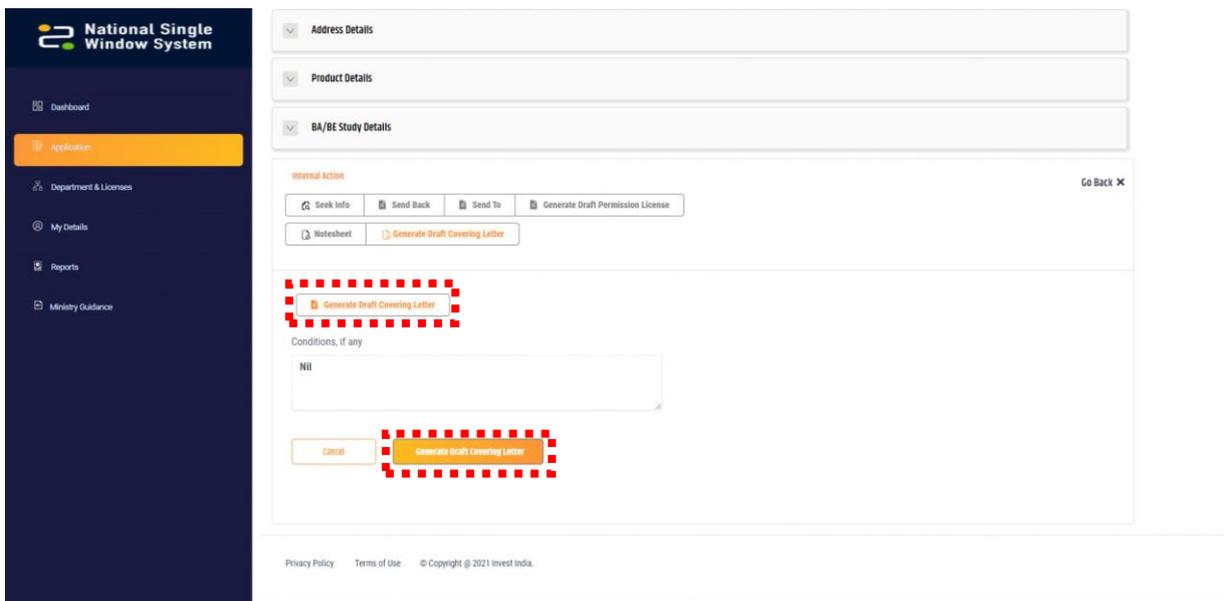
Name of Drug/Formulation	Brand Name	Class	Quantity	Unit
<input type="text" value="vbvb"/>	<input type="text" value=""/>	<input type="text" value="Analgesic Drugs"/>	<input type="text" value="34353"/>	<input type="text" value="Aerosol"/>

❖ The Draft License will be generated

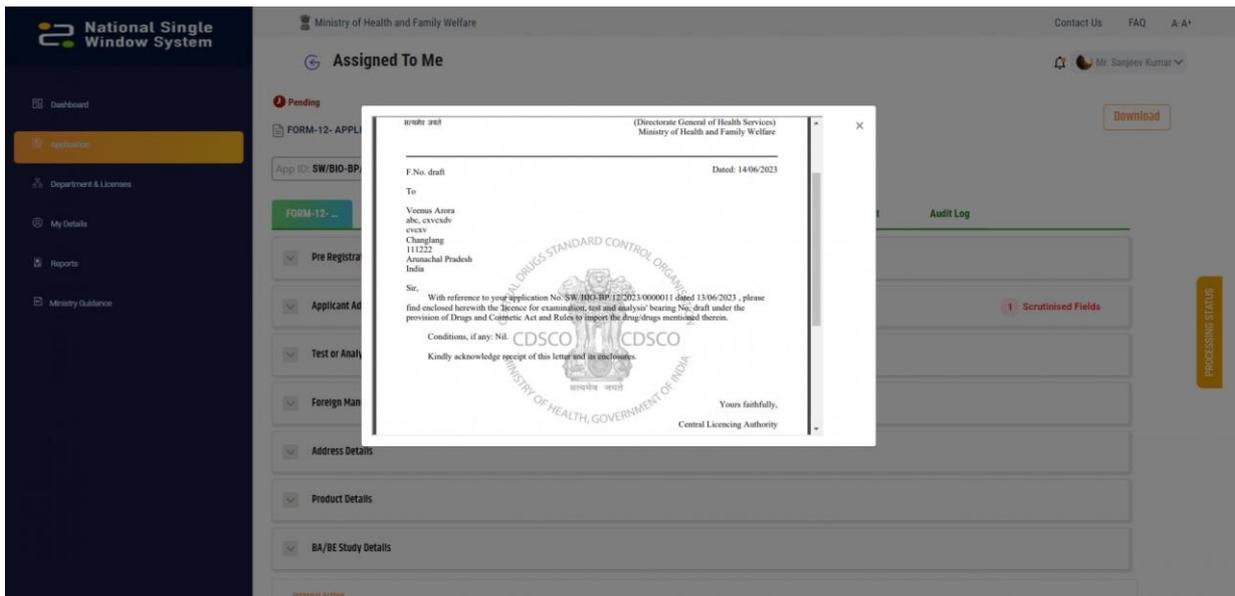


### 3.2.1.10 Generate Draft Covering Letter

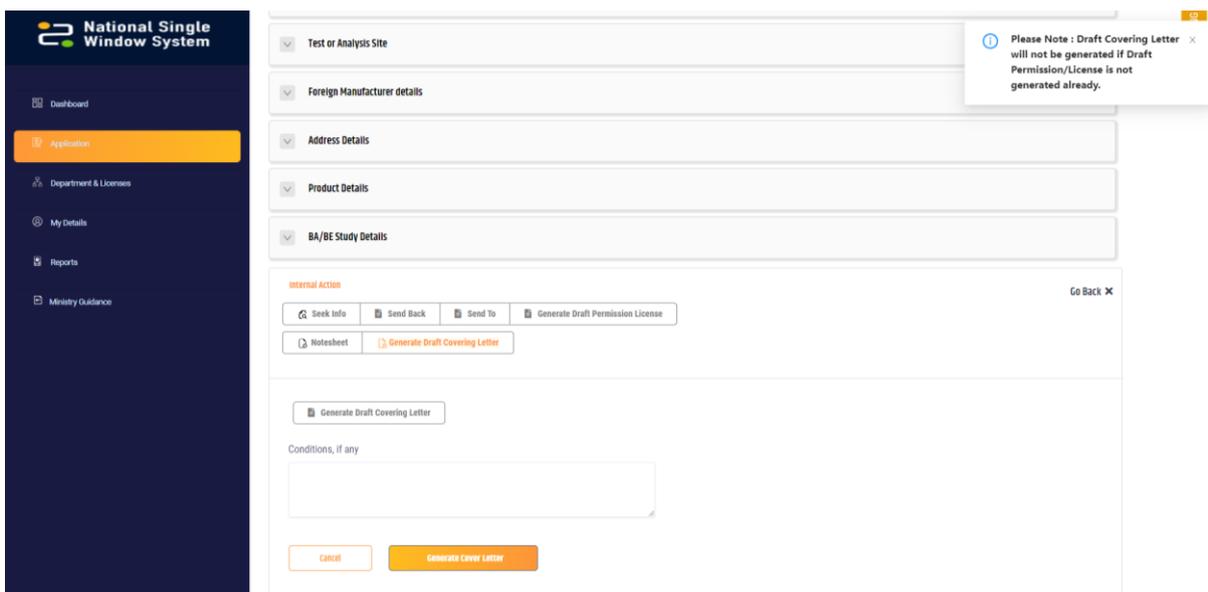
Ministry User can generate Draft Covering Letter using this option. Click on the buttons shown and add remarks.



The document will be generated



Condition: In case the user wants to “Generate Draft Covering Letter” , the ministry user has to first generate the “Draft Permission License” first. Otherwise, user will be provided with such a message



### 3.2.1.11 Approve Application

In case final level Ministry User finds the Application correct they would provide Final Approval using this option attaching the License Certificate.

User has to first generate the “Generate Permission/License” for such Approval

### 3.2.1.12 Reject Application

In case the ministry user is the final approver they would provide Final Rejection using the “Reject Application” option.

### 3.2.1.13 Generate Permission/License

- ❖ Ministry user can generate final license using this option. User can click on the button and update or edit the required details.

**National Single Window System**

- Dashboard
- Application**
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

**Internal Action** Go Back X

RegistrationNumber <b>SW/BIO-BP/11/2023/000002</b>	Name of the Applicant <b>Veenus Arora</b>
Designation <b>Chairman</b>	Applicant address 1 <b>abc</b>
Applicant address 2 <b>cvxcxv</b>	Applicant Country <b>India</b>
Applicant State <b>Arunachal Pradesh</b>	Applicant District <b>Changlang</b>
Applicant City <b>cvxcv</b>	Applicant Pincode <b>111222</b>
Name of the Foreign Manufacturer <b>cvxcv</b>	Address Line 1 <b>cvxc</b>
Address Line 2 <b>xcv</b>	State/Province/Region <b>xcvxc</b>

❖ Click on “Generate Final Permission License” as shown

**National Single Window System**

- Dashboard
- Application**
- Department & Licenses
- My Details
- Reports
- Ministry Guidance

**Internal Action** Go Back X

RegistrationNumber <b>SW/BIO-BP/11/2023/000002</b>	Name of the Applicant <b>Veenus Arora</b>
Designation <b>Chairman</b>	Applicant address 1 <b>abc</b>
Applicant address 2 <b>cvxcxv</b>	Applicant Country <b>India</b>
Applicant State <b>Arunachal Pradesh</b>	Applicant District <b>Changlang</b>
Applicant City <b>cvxcv</b>	Applicant Pincode <b>111222</b>
Name of the Foreign Manufacturer <b>cvxcv</b>	Address Line 1 <b>cvxc</b>
Address Line 2 <b>xcv</b>	State/Province/Region <b>xcvxc</b>
City	Foreign Manufacturer Country

❖ Click on “Generate Certificate” on bottom of the page

City:  Foreign Manufacturer Country:

Zip/Postal code:  Landline No:

Fax No:  Name of the site:

Address:  Select Department:

**Product Details**

Name of Drug/Formulation	Brand Name	Class	Quantity	Unit
<input type="text" value="vbvb"/>	<input type="text"/>	<input type="text" value="Analgesic Drugs"/>	<input type="text" value="34353"/>	<input type="text" value="Aerosol"/>

❖ The Final License will be generated

**Form 11**  
[See Rule 33]  
**LICENCE TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST OR ANALYSIS**

Number of Licence: **SW/BIO-BP/11/2023/000002**

I, Veenus Arora (Chairman), of abc, cxvxdv, India, Arunachal Pradesh, Changlang, cxv-111222 is hereby licensed to import from cxvxc, cxvxc, xcv, cxvxc, xcv, American Samoa -cxvxc, 1222222, 344555 the drugs specified below for the purposes of examination, test or analysis at cxvxc, cxvxc or in such other places as the licensing authority may from time to time authorize.

2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

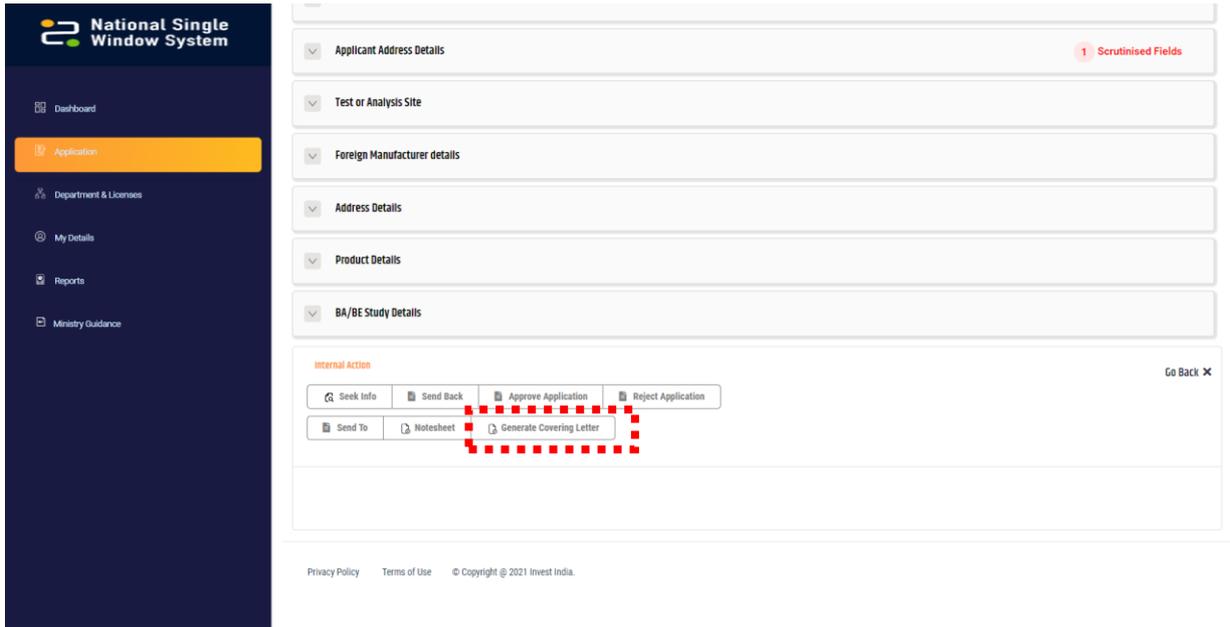
3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below:

S	Name of drugs	Brand Name	Class of Drug	Quantity which may be imported
N				
O				
.				
.				

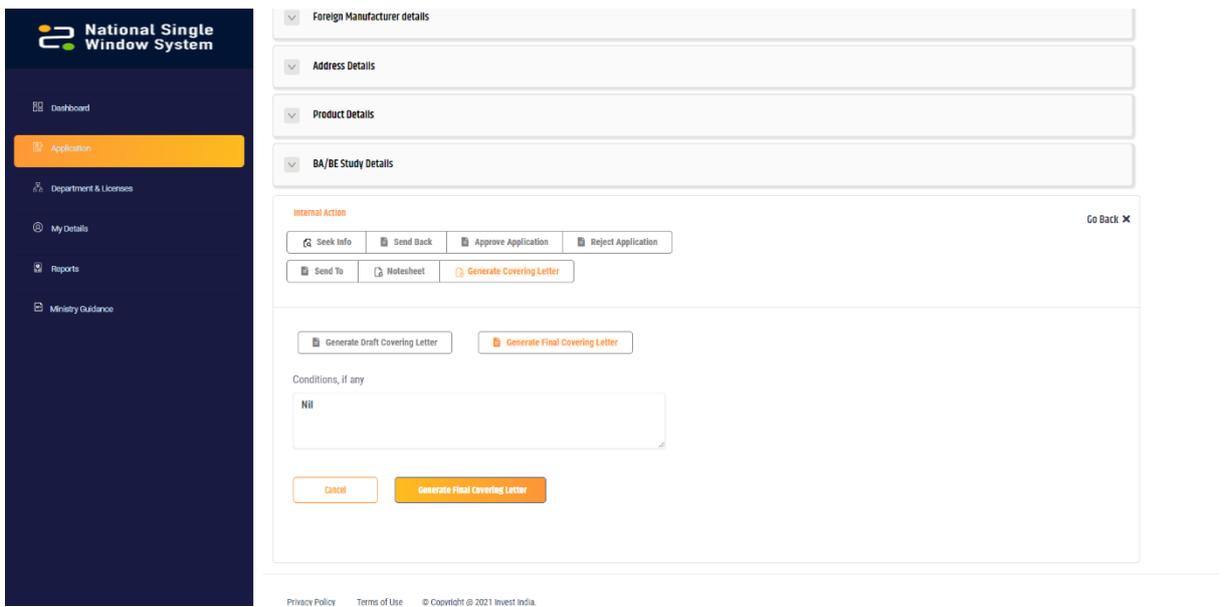
DRUGS STANDARD CONTROL ORG

### 3.2.1.14 Generate Covering Letter

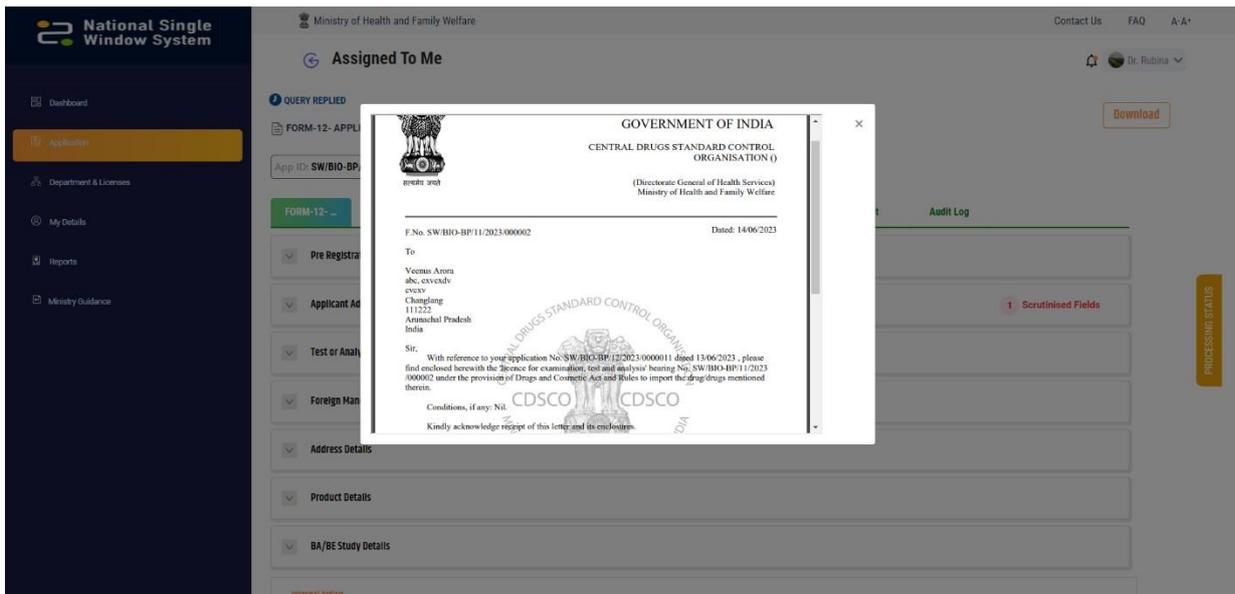
Ministry User can generate Final Covering Letter using this option.



Click on the buttons shown and add remarks.



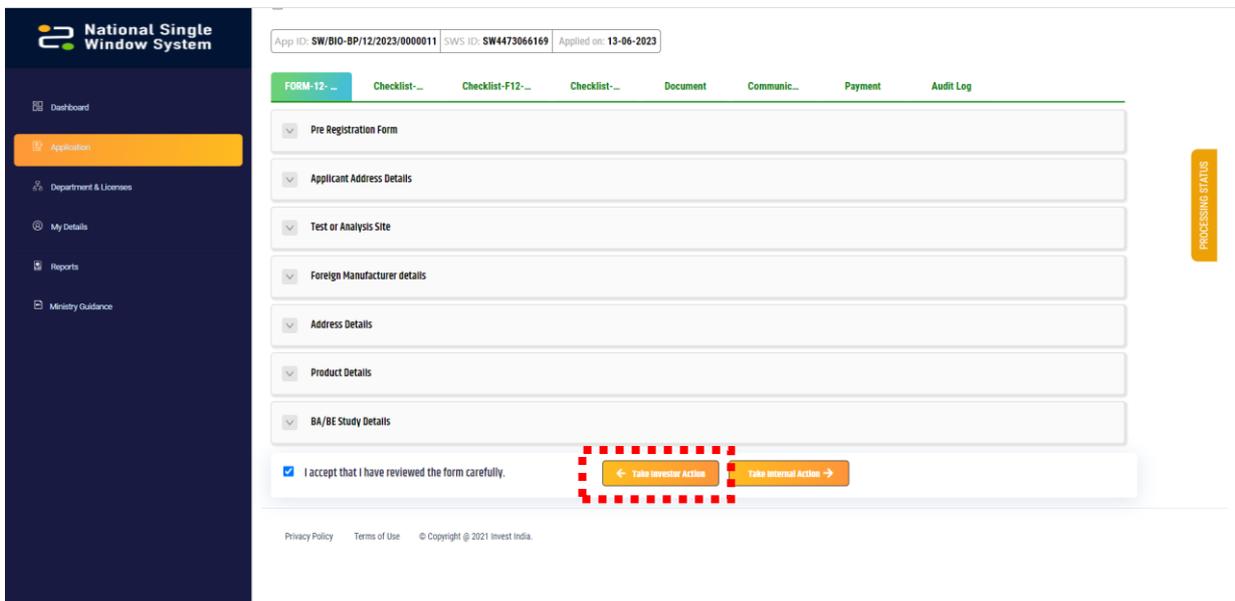
The document will be generated



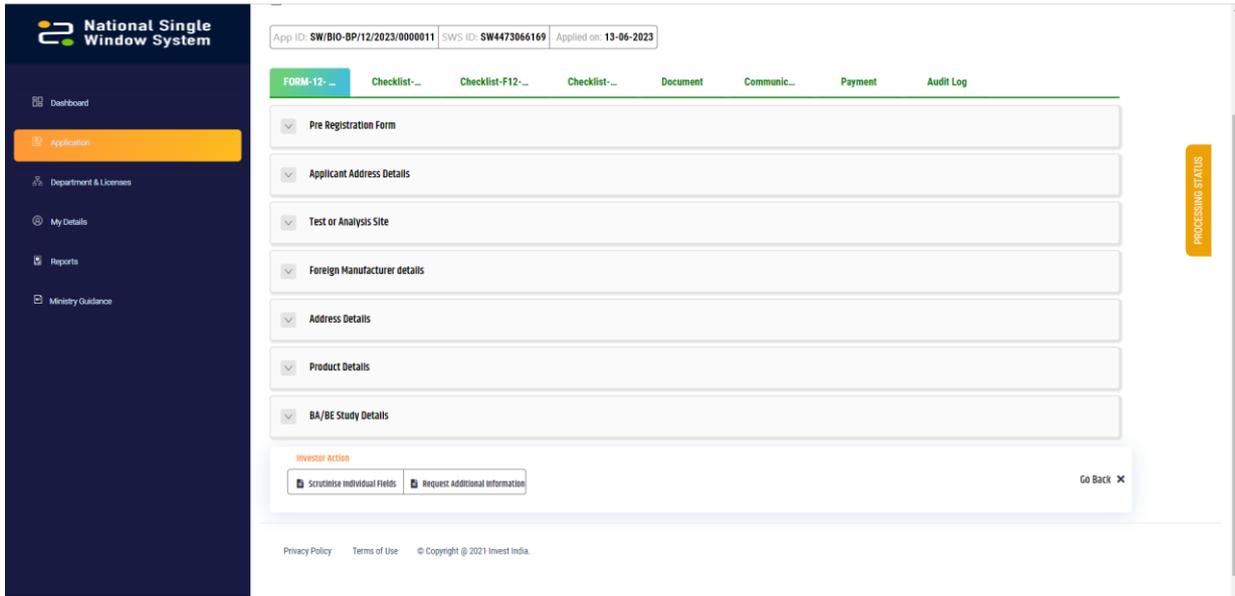
Condition: In case the user wants to “Generate Covering Letter” , the ministry user has to first generate the “Permission License” first.

### 3.2.2 Take Investor Action

In order to have communication with the investor, user needs to click on “Take Investor Action”



User will be provided with two options.

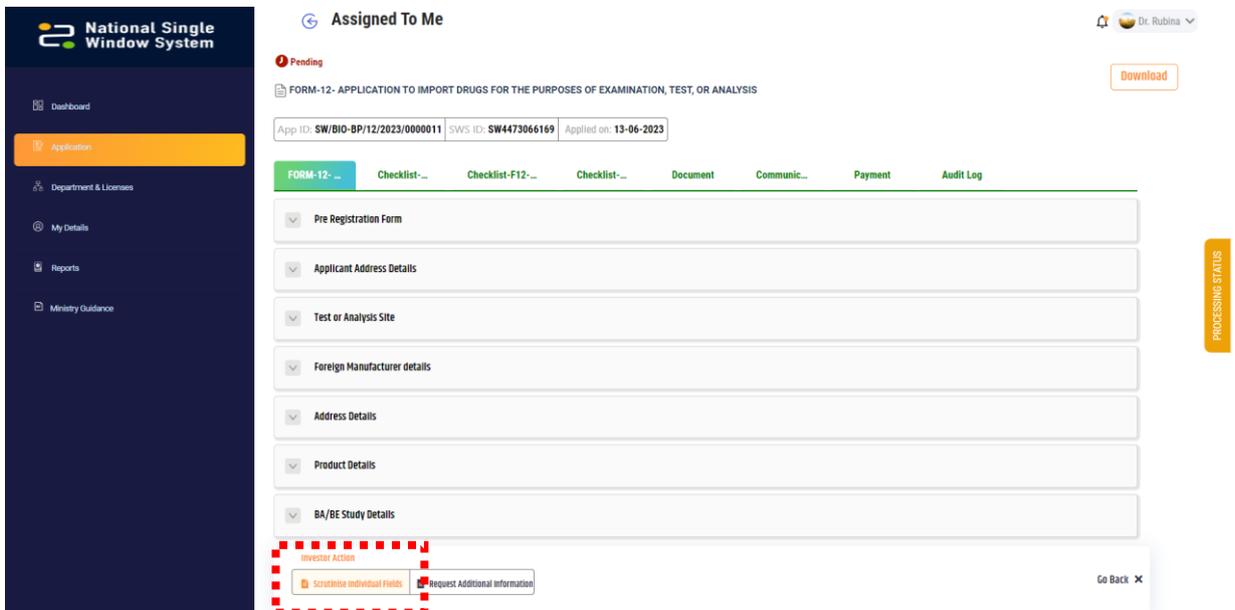


### 3.2.2.1 Scrutinize Individual Fields

Scrutiny process is a functionality added by NSWS in the Mistry User's Dashboard which is used as an intimation sent by Ministry to the Investor in cases where the Ministry thinks that Investor has given incorrect information in any field(s). Consequently, the Investor will be given an option to re-fill those fields and Resubmit the Application. Note: User will have to generate Notesheet before performing such scrutiny.

Process for the same is captured below:

- ❖ Click on "Scrutinise individual fields".



- ❖ Click on the arrow for the desired section

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FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

App ID: SW/BIO-BP/12/2023/0000011 | SWS ID: SW4473066169 | Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Select All

Name of the Applicant	Veenus Arora	<input type="radio"/>
Designation	Chairman	<input type="radio"/>
City	ZXCXX	<input type="radio"/>
Address		
Address Line 1	abc	<input type="radio"/>
Address Line 2	cvxcvdr	<input type="radio"/>

PROCESSING STATUS

- ❖ Click on the Circle against the field(s) where action is required and add the required remarks and click on “Save”

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FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS

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FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Select All

Name of the Applicant	Veenus Arora	<input type="radio"/>
Please provide the full name of the applicant with proper salutation		
	Cancel Save	<input checked="" type="radio"/>
Designation	Chairman	<input type="radio"/>
City	ZXCXX	<input type="radio"/>
Address		
Address Line 1	abc	<input type="radio"/>

PROCESSING STATUS

- ❖ Finally click on “Submit Scrutiny” tab provided at the end of the page.

App ID: SW/BID-BP/12/2023/0000011 | SWS ID: SW4473066169 | Applied on: 13-06-2023

FORM-12-... Checklist-... Checklist-F12-... Checklist-... Document Communic... Payment Audit Log

Pre Registration Form

Applicant Address Details

Select All

Name of the Applicant: Venus Arora

Please provide the full name of the applicant with proper salutation

Cancel Save

Designation: Chairman

City: ZXCXX

Address: abc

Address Line 1: abc

Address Line 2:

PROCESSING STATUS

Add Generic Remarks Submit Scrutiny

- ❖ Ministry User can also add some remarks in case they want to explain the issue more clearly.

Reopen Form for Scrutiny

Add Generic Remarks

Type your remarks here

Note Maximum 2000 characters are allowed for remarks.

Save Remark

- ❖ The new input of the field will be visible on Ministry End once the investor will correct it and resubmit the Application.

Note: After the Investor resolves such query raised by Ministry user of any level, the application will automatically be assigned to the Reviewing Officer (Level 2).

### 3.2.2.2 Request Additional Information

- ❖ In case the Ministry User want some general clarifications from the investor they can use this option.
- ❖ Ministry User has to click on “Request Additional Information” button. Add the required remarks and send the request.

❖ Once the investor replies on it, the same will appear on the communication tab as shown below

### 3.3 Ministry Users and Actions they can perform

Level	Officer	Actions they can perform
1	N.O. (Nodal Officer)	<ul style="list-style-type: none"> <li>• Seek Info</li> <li>• Pull Back and Reassign</li> <li>• Send To</li> </ul>
2	R.O (Reviewing Officer)	<ul style="list-style-type: none"> <li>• Notesheet Generation</li> <li>• Forward to next level</li> <li>• Send To, Seek Info</li> <li>• Generate Draft Covering Letter</li> <li>• Generate Draft Permission/License</li> </ul>
3	N.O. (Nodal Officer)	<ul style="list-style-type: none"> <li>• Send To</li> <li>• Send Back</li> <li>• Seek Info</li> <li>• Generate Draft Covering Letter</li> <li>• Generate Draft Permission/License</li> <li>• Notesheet</li> </ul>
4	D.D.A. (Deputy Deciding Authority)	<ul style="list-style-type: none"> <li>• Send To</li> <li>• Send Back</li> <li>• Seek Info</li> <li>• Generate Draft Covering Letter</li> <li>• Generate Draft Permission/License</li> <li>• Notesheet</li> </ul>
5	D.A. (Deciding Authority)	<ul style="list-style-type: none"> <li>• Send To</li> <li>• Send Back</li> <li>• Seek Info</li> <li>• Generate Draft Covering Letter</li> <li>• Generate Draft Permission/License</li> <li>• Notesheet</li> </ul>
6	L.A. (Licensing Authority)	<ul style="list-style-type: none"> <li>• Send To</li> <li>• Send Back</li> <li>• Seek Info</li> <li>• Generate Draft Covering Letter</li> <li>• Notesheet</li> <li>• Approve</li> <li>• Reject</li> <li>• Generate Final Permission Letter</li> <li>• Generate Final Covering Letter</li> </ul>

## 4 Approval and Form Linking

Ministry User can also use the Ministry Dashboard for knowing the status of their Approvals for KYA and Form Linking. Ministry User upon login to the Ministry Dashboard should select the “Department and Licenses” tab.

The screenshot shows the Ministry Dashboard Overview page. The left sidebar contains the 'National Single Window System' logo and navigation options: Dashboard, Application, Department & Licenses (highlighted with a red dashed box), My Details, Reports, and Ministry Guidance. The main content area is titled 'Ministry of Health and Family Welfare' and includes a user profile for 'Dr. Rubina'. The 'Overview' section displays four summary cards: '0 Total Applications', '0 Applications Completed', '0 Applications Pending with Ministry', and '0 Applications Pending with Applicant'. Below these are two tables: 'Applications by status' and 'Overview'. The 'Applications by status' table has columns for Approvals, New Applications, Applications In Process, and Applications Completed. The 'Overview' table shows 'No data found'. At the bottom, there is a 'No. of Applications by Monthly' chart.

The page will show the list of Approvals under CDSCO. The table will show status of each approval for their KYA and Form Alignment.

The screenshot shows the Ministry Dashboard 'Department and Licenses' page. The left sidebar is the same as in the previous screenshot. The main content area is titled 'Ministry of Health and Family Welfare' and includes a user profile for 'Dr. Rubina'. The page displays 'Directorate General of Health Services (62)'. Below this is a table with columns for 'Approval/Registration', 'KYA Aligned', and 'Form Uploaded'. The table lists various applications and their corresponding KYA and Form Uploaded statuses.

Approval/Registration	KYA Aligned	Form Uploaded
<input type="checkbox"/> CDSCO Checklists: Bulk Drug - Endorse	<span style="color: red;">⊘</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> CDSCO Checklists: Bulk Drug - Fresh Applications	<span style="color: red;">⊘</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> CDSCO Checklists: Fresh Formulation - Endorse	<span style="color: red;">⊘</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> CDSCO Checklists: Fresh Formulation - Fresh Applications	<span style="color: red;">⊘</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study	<span style="color: green;">⊙</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> CT-16 Application for grant of license to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study	<span style="color: green;">⊙</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> Form 8 (See rule 24A) Application for License to Import Drugs(Excluding those specified in schedule X) to the Drugs and Cosmetics rules, 1945	<span style="color: green;">⊙</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> Form CT-10 Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis	<span style="color: green;">⊙</span>	<span style="color: green;">⊙</span>
<input type="checkbox"/> Form CT-12 - Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study	<span style="color: green;">⊙</span>	<span style="color: green;">⊙</span>

To know which forms are linked to an Approval the User should click on the Approval name (If the Form Uploaded Status is given as Yes). Clicking on the form name will open it in “Preview Mode”.

**National Single Window System**

- Dashboard
- Application
- Department & Licenses**
- My Details
- Reports
- Ministry Guidance

Directorate General of Health Services (62)

Approval/Registration	KYA Aligned	Form Uploaded
<input type="checkbox"/> CDSO Checklists: Bulk Drug - Endorse		
<input type="checkbox"/> CDSO Checklists: Bulk Drug - Fresh Applications		
<input type="checkbox"/> CDSO Checklists: Fresh Formulation - Endorse		
<input type="checkbox"/> CDSO Checklists: Fresh Formulation - Fresh Applications		
<input type="checkbox"/> <b>CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study</b>		
<b>Form CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study</b> Checklist CT13-IND-FFBD-Test & Analysis Checklist CT13-IND-FFBD-Clinical Trial Checklist CT13-SND-FFBD-Test & Analysis Checklist CT13-SND-FFBD-Clinical Trial/ABE Checklist CT13-BIO-Vaccine-FFBD-Test & Analysis Checklist CT13-BIO-IONA-FFBD-Test & Analysis Checklist CT13-BIO-IONA-FFBD-Clinical Trial Checklist CT13-ND-FFBD-Test & Analysis Checklist CT13-ND-FFBD-Clinical Trial Checklist CT13-BIO-Vaccine-FFBD-Clinical Trial		
<input type="checkbox"/> CT-16 Application for grant of license to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study		

## 5 NSWS Support Center

NSWS has set-up a dedicated team for catering to the queries by Ministry personnel. NSWS also answers the queries of the users through the FAQs provided on the Help Page.

The SPOC (Single Point of Contact) from NSWS for CDSCO are

Mr. Agni Jasthi <ganesh.agni@investindia.org.in>

Mr. Vaibhav Yadav <vaibhavyadav@investindia.org.in>

Ministry users can directly coordinate with the SPOC for clarification of their queries.

If the Ministry wants to change anything on their Ministry Portals then they can contact the Invest India SPOC for the same.

--- END OF GUIDE ---