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

Notice

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

Date: **1 6 JAN 2024**

Subject – Launching of additional Forms on National Single Window System (NSWS) Portal- reg.

This is in continuation to this office notice dated 01.01.2024 whereby 3 Forms i.e. MD-01, MD-12 and MD-16 were made 'Live' on NSWS portal w.e.f. 01.01.2024.

Now following additional Forms have also been developed and will be made 'Live' on NSWS w.e.f. **16.01.2024**:-

1. 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- CT-10.

2. 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-CT-12.

3. 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-CT-13.

4. Application for grant of licence to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis -CT-16.

Further Form 12 i.e. 'Application for licence to import drugs for purpose of examination, test or analysis' will also be made 'Live' on **24.01.2024**.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said five activities through NSWS portal only and the existing SUGAM online portal for the said activities will be disabled w.e.f. **10.02.2024.**

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

National Single Window System

Table of Contents

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

National Single Window System (https://www.nsws.gov.in/)

National Single
Window System

How to view, add approval from 'All Approvals'

Hover over '**Central Approvals**' and click on '**All Approvals**'

Click on **"Add to Dashboard"**

Select **"Directorate General of Health Services"** from the list of Departments

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MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

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National Single
Window System

How to view, add approval through Central KYA

Click on '**Know Your Approvals**' on the NSWS homepage

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

National Single Window System

How to add identified approval to the Dashboard

उद्योग संवर्धन और आंतरिक व्यापार विभाग
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE | INVEST INDIA
NATIONAL INVESTMENT PROMOTION & FACILITATION AGENCY

About   FAQs   Guide   Contact   A   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 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 pharma
For Business Activity Details ○ Issued by Directorate Gene

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.

> Users will be redirected to the '**Sign In**' Page

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

Andhra Pradesh   Arunachal Pradesh   Government of Bihar   Government of Gujarat

Government of Karnataka   Government of Goa
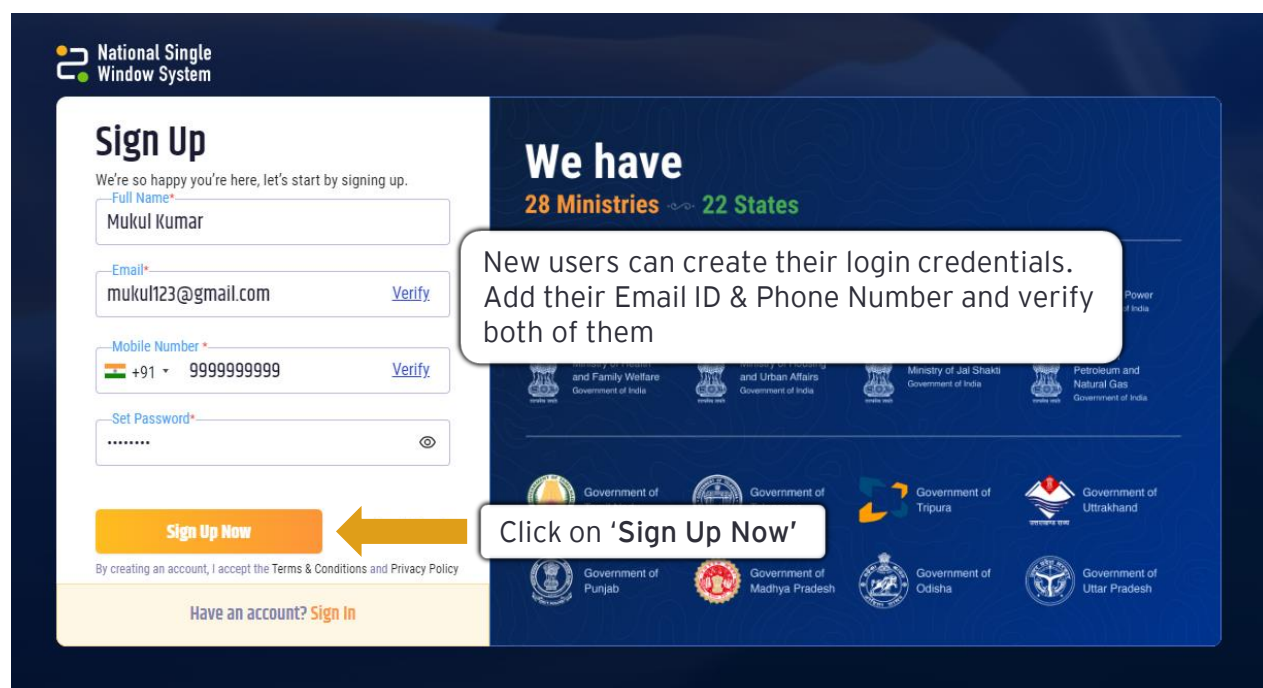
> Existing users can '**Sign In**' with their credentials

> 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
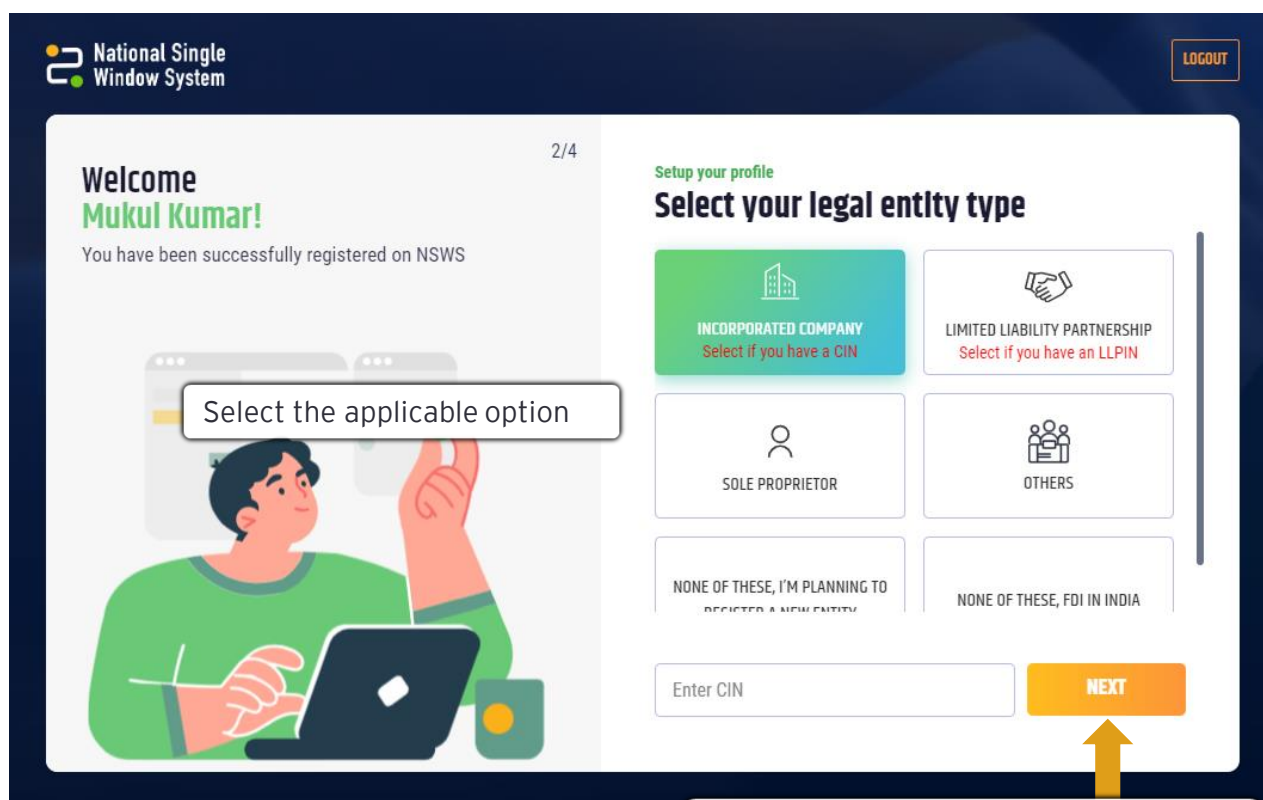
Set Password*
••••••••   👁

Sign Up Now

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

Have an account? **Sign In**

We have
28 Ministries ∽ **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'**

National Single Window System

LOGOUT

2/4

Welcome
Mukul Kumar!

You have been successfully registered on NSWS

Select the applicable option

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**

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

How to fill the application form

Add the details in the Profile section

Click on '**Apply Now**' to proceed with the Application

Click here to expand all section at once

Navigate through different forms for the approval from here

Click on the downward arrow against the section names to expand and fill the form

National Single Window System (https://www.nsws.gov.in/)

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

How to fill the application form

Pre Registration Form

Select Department *

Biological - Blood Products

The '*' indicates a mandatory field to be filled by the user

CDSCO 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

Some Data will be pre-populated as filled up in the profile

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

This button will create a duplicate section for the selected 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 *

National Single Window System

How to fill the application form

This button will create a duplicate group for the selected group

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

National Single Window System

How to fill the application form

Yes ○ No ○		Yes ○ No ○

An explanation about whom to contact for trial related queries, ri~

○ Yes ○ No

The anticipated prorated payment, if any, to the Subject for partic

○ Yes ○ No

Subject's responsibilities on participation in the trial

○ Yes ○ No

Statement that participation is voluntary, that the Subject can wit

○ Yes ○ No

PI's undertaking

○ Yes ○ No

International prescribing information

○ Yes ○ No

Justification ⓘ

Next Form   **Save as Draft**   ⬅ Use this button to save the progress of the filled up application

1 **2**   **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) *

CDSCO Checklist ▼   Browse File   ⬅ Select Document type and Click on '**Browse File**' to add attachments

Supported files are PDF

Name of Applicant (Applicant Details) - Remarks *

2. Drug Details

Drug Details *

Select Document Type ▼   Browse F   ➡ ⬇   This button indicates that the user needs to Download a format, fill it up and upload the same on that particular field

Supported files are PDF

Drug Details - Remarks *

How to fill the application form

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
*

Browse File

Supported files are PDF
dummy.pdf

Remarks *

Document

10. Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19

Performance evaluation report from a laboratory designated under sub-rule (1) of rule 19 *

Browse File

Supported files are PDF
dummy.pdf

Remarks *

Uploaded

< **Review & Submit**

Once filled, click on Review and Submit

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, ...

2 3 4

Application Fee
₹5,000 ⓘ

Applicable fee will be visible here

Pre Registration Form	
Select Department	Biological - Blood Products
Purpose of Application	For Examination, Test or Analysis
CDSCO Applicable zone/HQ	CDSCO 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

| Applicant Address Details | |

☑ I have reviewed all the information provided by me and confirm that it is correct to the best of my knowledge.

Review the application and click here for final submission

Pay & Submit   Back to edit details

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INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

National Single Window System (https://www.nsws.gov.in/)

National Single Window System

How to fill the application form

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

Pay the amount using the Bharatkosh portal

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INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

National Single Window System

How to fill the application form

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

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

Provider *
Microsoft Windows Store

Certificate *
Class 3 Individual Test

Token Password *
····

Sign & Submit   Cancel

Document for sign

MOH_Certificate for Registration

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

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

National Single Window System

How to fill the application form

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* Q | CT MY DASHBOARD

My Dashboard   My Documents   Members   Profile

My Dashboard
Manage and track the status of your application

1 My Central Approvals   0 My State Approvals

Central Approvals In List (1 approvals)

| 0 Not Applied | 1 Submitted To Ministry | 0 Assigned To Me | 0 Approved | 0 Rejected |

Search by Approval Name   Add More 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

---

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* Q | CT MY DASHBOARD

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

Upload the documents, add the information

« | Review & Submit | Save as Draft

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

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

National Single Window System (https://www.nsws.gov.in/)

National Single Window System

How to view the application form (Legal Form)

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

The legal form can be previewed/downloaded

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INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

National Single Window System (https://www.nsws.gov.in/)

National Single
Window System

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 Reponses 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...   2   3   4   5   →

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

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🔍 🔔 **D** **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...   2   3   4   5   →

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

User will land on checklist enabled for them to fill up

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

National Single Window System

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

- -

Have any further questions?
Please submit your queries and feedback on:

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

Email: contactus-nsws@investindia.org.in
Ph: 1800 102 5841
(Monday - Saturday, 9am - 6pm)

Last Updated on 14 March 2023

National Single Window System (https://www.nsws.gov.in/)

National Single Window System (NSWS)

CDSCO

Ministry User Guide

Table of Contents

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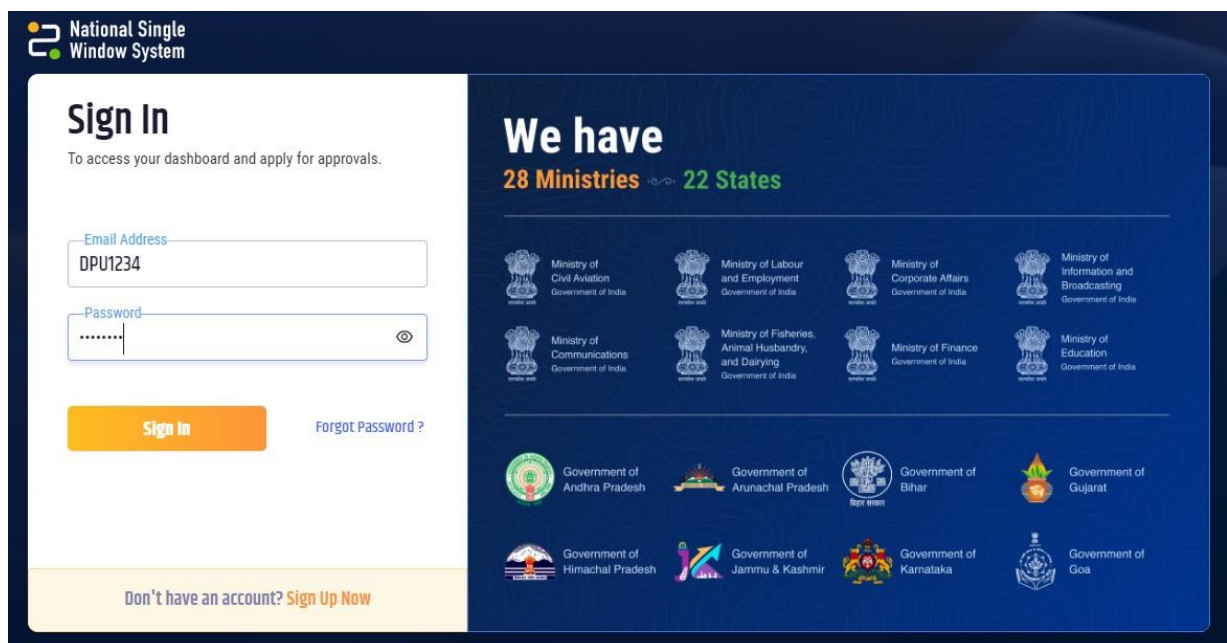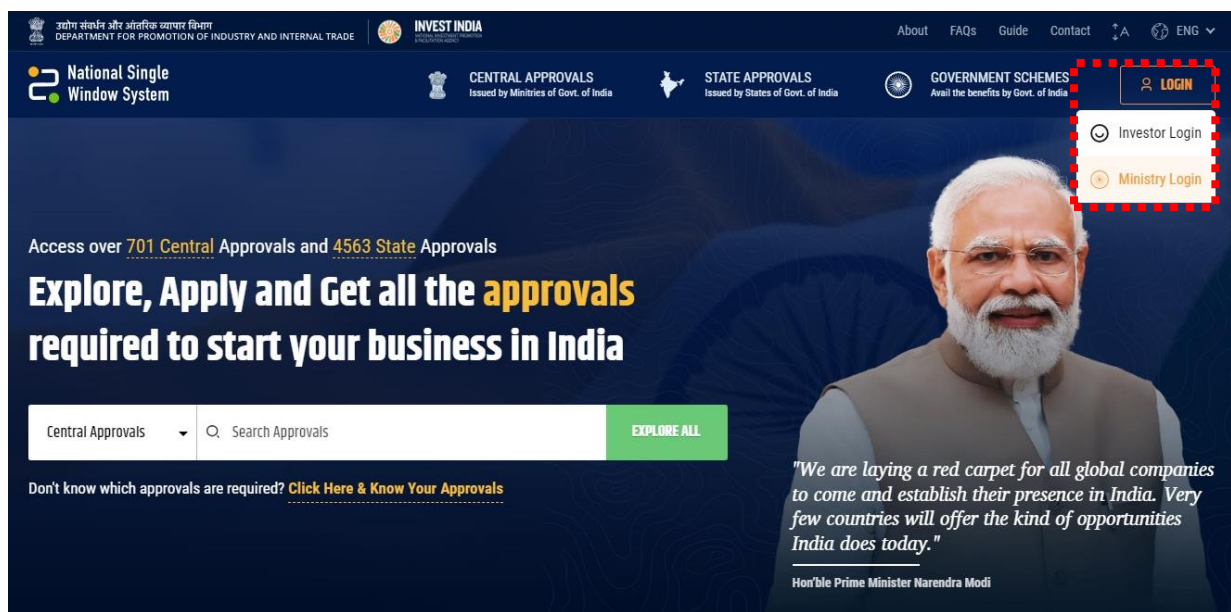
The Ministry Dashboard on Login: Upon logging-in the Ministry User will be redirected to the Dashboard. The Dashboard contains the count of Applications:

❖ *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.

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

🌸 **INVEST INDIA**

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

Ministry User can navigate the through a single form vertically.

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.
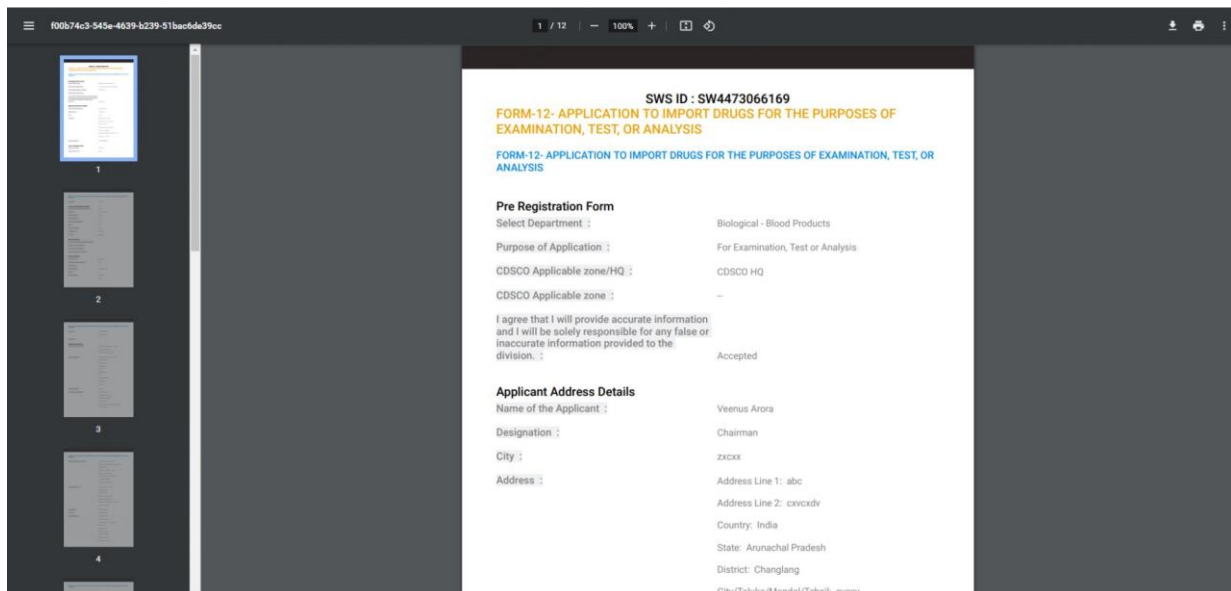
3.1.4 Download Application and Documents

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	Transaction Date	Transaction Time	
T1686645848691A53144L4194P19114	Tue Jun 13 2023	2:14:08 PM	⬇ Download Receipt

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.

3.1.8 Audit Log

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

3.2   Process for Application Review

Ministry User will be provided with two tabs as shown below

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.

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.

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
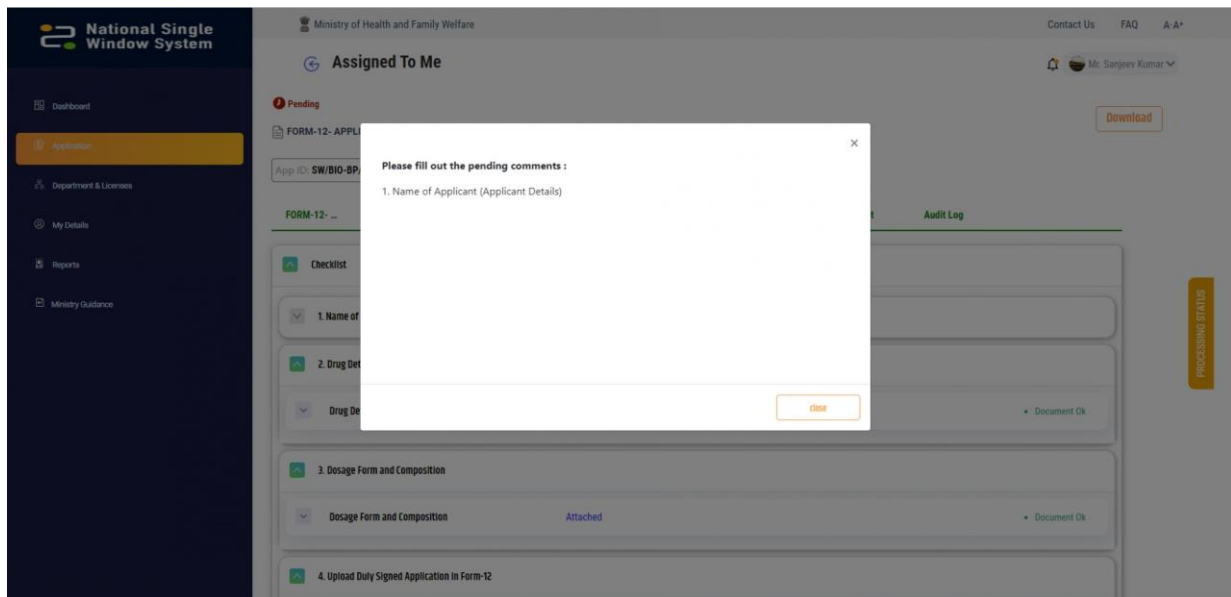
3.2.1.7 Send Back

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

3.2.1.8 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

❖ Click on "Generate Certificate" on bottom of the page

❖ 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.

❖ Click on "Generate Final Permission License" as shown

❖ Click on "Generate Certificate" on bottom of the page

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❖   The Final License will be generated

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.
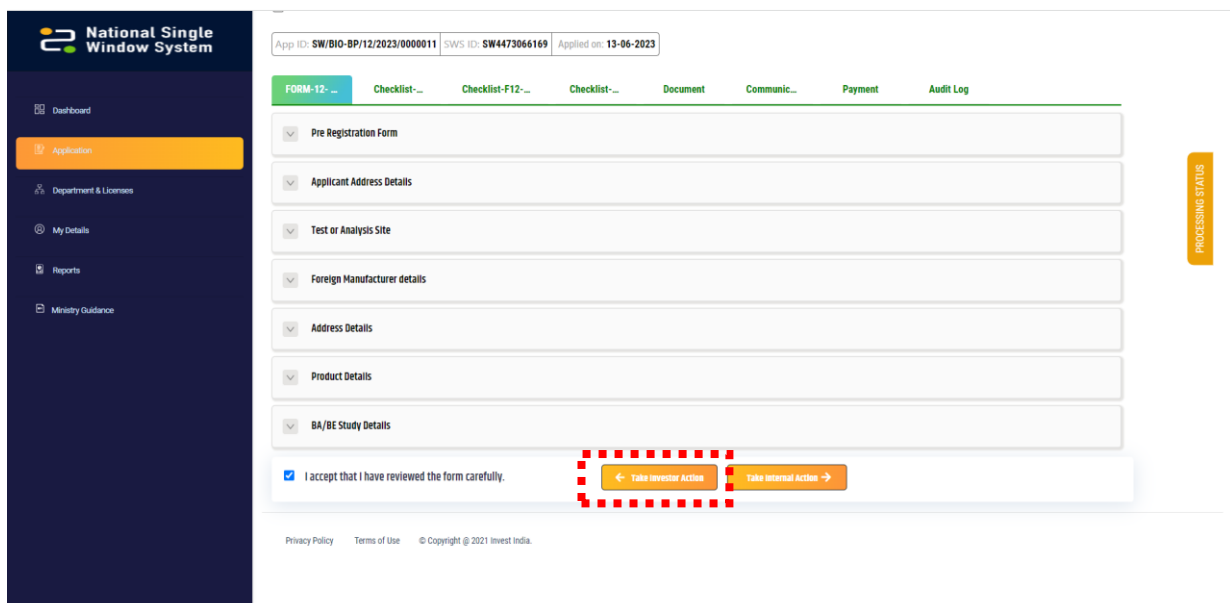
Process for the same is captured below:

❖   Click on "Scrutinise individual fields".

❖   Click on the arrow for the desired section

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

❖ Finally click on "Submit Scrutiny" tab provided at the end of the page.

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

❖ 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 commination tab as shown below

3.3 Ministry Users and Actions they can perform

Level	Officer	Actions they can perform
1	N.O. (Nodal Officer)	• Seek Info • Pull Back and Reassign • Send To
2	R.O (Reviewing Officer)	• Notesheet Generation • Forward to next level • Send To, Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License
3	N.O. (Nodal Officer)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
4	D.D.A. (Deputy Deciding Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
5	D.A. (Deciding Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
6	L.A. (Licensing Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Notesheet • Approve • Reject • Generate Final Permission Letter • Generate Final Covering Letter

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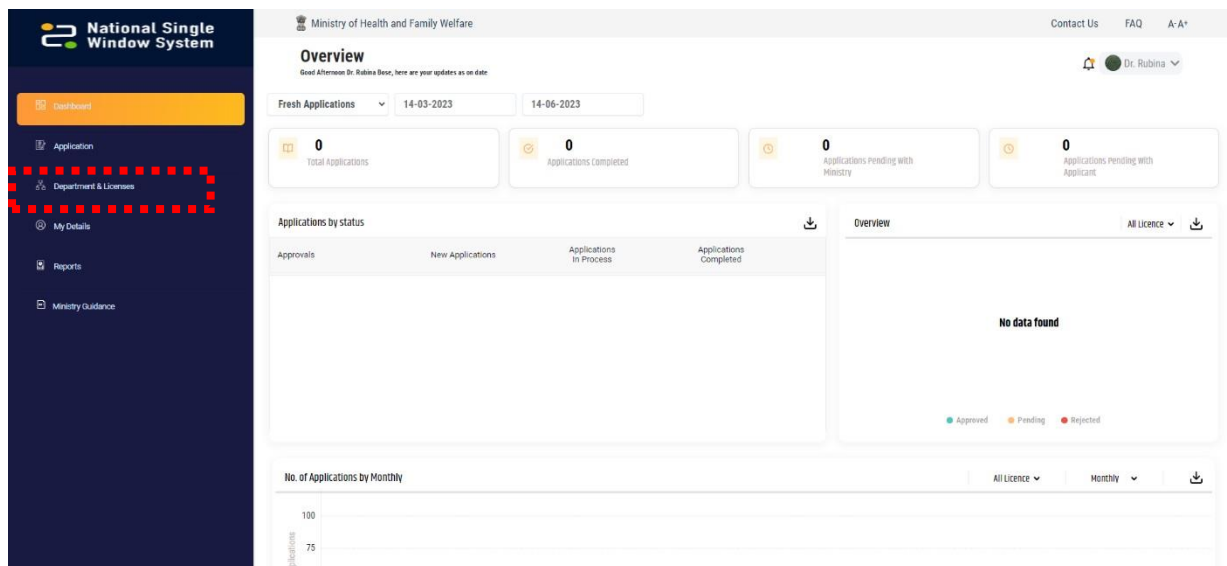
The page will show the list of Approvals under CDSCO. The table will show status of each approval for their KYA and Form Alignment.

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
⊞ CDSCO Checklists: Bulk Drug - Endorse	⊗	⊘
⊞ CDSCO Checklists: Bulk Drug - Fresh Applications	⊗	⊘
⊞ CDSCO Checklists: Fresh Formulation - Endorse	⊗	⊘
⊞ CDSCO Checklists: Fresh Formulation - Fresh Applications	⊗	⊘
⊟ 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	⊘	⊘

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

Checklist CT13-IND-FFBD-Test & Analysis
Checklist CT13-IND-FFBD-Clinical Trial
Checklist CT13-SND-FFBD-Test & Analysis
Checklist CT13-SND-FFBD-Clinical TrialBABE
Checklist CT13-BIO-Vaccine-FFBD-Test & Analysis
Checklist CT13-BIO-rDNA-FFBD- Test & Analysis
Checklist CT13-BIO-rDNA-FFBD-Clinical Trial
Checklist CT13-ND-FFBD-Test & Analysis
Checklist CT13-ND-FFBD-Clinical Trial
Checklist CT13-BIO-Vaccine-FFBD-Clinical Trial

| ⊞ 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 ---