

# How to Submit an Establishment Registration

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OC/OU DLC/DRLB

CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT  
September 28, 2023

# Learning Objectives

- Determine who registers and when
- Create and submit an Establishment Registration





# Who Must Register?

- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the United States (21 CFR 207.17).
- Certain exemptions are included under 21 CFR 207.13.



# When to Register?

§207.21 When must initial registration information be provided?

- (a) Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment.
- (b) Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.

This application is for **TESTING** only. Any submissions made in this application are not officially recognized by the FDA. Use [direct.fda.gov](https://direct.fda.gov) to make official submissions to FDA.

### LOGIN

Username:

rsamuel2

Password:

\*\*\*\*\*

*Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*

I Understand.

**LOGIN**

[Forgot your password?](#)

### QUICK LINKS

[Register With CDER Direct](#)

[Resources](#)

[Tutorials](#)

[Help Desk](#)

[FAQs](#)

### GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your **Username** and **Password**.

**WARNING:** This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

**Is your computer secure?** Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

**Browser Compatibility:** The CDER Direct portal currently works best with the following browsers:

- Microsoft Edge
- Firefox version 28 and above
- Google Chrome
- Safari 10.0.1 and above

### NOTIFICATIONS



Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back in to the CDER Direct Electronic Submissions Portal. You will also receive an email from FDA when the processing is complete.

Home > Establishment Registration

- SUBMISSIONS**  
**(ADD SUBMISSION TYPE)**
- NDC Labeler Code Request
  - Establishment Registration
  - Product Listing and Certification
  - NDC Reservation

### ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For general questions regarding electronic drug registration and listing, contact [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov).

GO
ACTIONS ▾

SEARCH ESTABLISHMENT
CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
AWAITING ACCEPTANCE	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	987654321	Wonder Pharma	ESTABLISHMENT REGISTRATION	DETAILS	Regie Samuel	30-AUG-2023 15:31:34	-
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	888888888	Wonder Pharma China	ESTABLISHMENT REGISTRATION	DETAILS	Regie Samuel	01-OCT-2018 11:55:10	-

1 - 2



**CERTIFICATION OF FDA REGISTRATION**  
Fiscal Year 2020

This certifies that:  
**GUANGDONG QINJING TESTING CO., LTD.**  
Floor 2, Building B and Floor 3, Building G, No. 30, Development Zone,  
Lizha, Paiting City, Jieyang, Guangdong, 515300, CHINA

has complied with the FDA Establishment Registration and Device Listing with the US Food & Drug Administration through:  
Shenzhen CCT Testing Technology Co., Ltd.   
Owner/Operator Number: 10602783

Device Listing#	Listing No.	Code	Device Name	Proprietary Name
0373			MASK, SCAFFOLDING	FACE MASK, DISPOSABLE FACE MASK, SURGICAL MASK, DISPOSABLE SURGICAL FACE MASK

0373 certifies that each registration number, device name and description of the device and the device's essential use are correct and complete. The registration number is the unique identifier for the device and is used for identification purposes. The device name and description are used for identification purposes. The device name and description are used for identification purposes. The device name and description are used for identification purposes.

Shenzhen CCT Testing Technology Co., Ltd.  
10602783  
www.cct-testing.com



**CERTIFICATION OF FDA REGISTRATION**  
2020

This certifies that:  
**ZHEJIANG JINSHIANG COSMETICS BEAR CO., LTD**  
No.3 Anshang Road Wanzhang Street, Yiwu, 322000, China

NDC Labeler Code: 73906    Device Number: 423989167

Was registered with U.S. FOOD & Drug Administration Center of Devices and Radiological Health pursuant to the Code of Federal Regulations 21 CFR 301.307. Such registration has been verified with the registration's confirmation by Shenzhen CCT Testing Technology Co., Ltd.

Registration Name	Head Number	Registration No.	Registration Date	Registration Expiration Date
1173000001-01	01	1173000001-01	11/19/2019	11/19/2021
1173000001-02	02	1173000001-02	11/19/2019	11/19/2021
1173000001-03	03	1173000001-03	11/19/2019	11/19/2021
1173000001-04	04	1173000001-04	11/19/2019	11/19/2021
1173000001-05	05	1173000001-05	11/19/2019	11/19/2021
1173000001-06	06	1173000001-06	11/19/2019	11/19/2021
1173000001-07	07	1173000001-07	11/19/2019	11/19/2021
1173000001-08	08	1173000001-08	11/19/2019	11/19/2021
1173000001-09	09	1173000001-09	11/19/2019	11/19/2021
1173000001-10	10	1173000001-10	11/19/2019	11/19/2021
1173000001-11	11	1173000001-11	11/19/2019	11/19/2021
1173000001-12	12	1173000001-12	11/19/2019	11/19/2021

Note: The annual registration renewal period is October 1 - December 31.

Shenzhen CCT Testing Technology Co., Ltd.  
10602783  
www.cct-testing.com

**CERTIFICATE OF REGISTRATION**  
2020

This certifies that:  
**Dibar Nutricional S. de R.L. de C.V.**  
Escalafito No. 20 Col Puerto Buenavista  
Morelia, MI 58302  
Mexico

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Biologics Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereby by Registrar Corp.

U.S. FDA Registration No.: 1060486822  
U.S. Agent for FDA: Registrar Corp  
144 Research Drive, Hampton, Virginia, 23666, USA  
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above listed facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Biologics Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date listed, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2020, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representation or warranty, nor does this certificate make any representation or warranty to any person or entity other than the central certificate holder. An annual certificate renewal is needed. Registrar Corp assumes no liability for any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize or contribute to registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

**Registrar Corp**  
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*D. Robinson*  
David Robinson  
Executive Director  
Registrar Corp  
Date: 10/26/2020 10:08 AM



# Challenge Question

**Who should not register as a drug establishment?**

- A. Repackagers
- B. Private Label Distributors
- C. Contract Manufacturers
- D. Manufacturers



# Summary



- Register on time – it's easy!
- You can manage multiple establishment locations on one Establishment Registration
- Ensure your DUNS information is up-to-date with D&B
- Firms that are solely Private Label Distributors should not register as a drug establishment

**Thank You for  
Registering!**

**Contact Us:**

**[eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov)**



**U.S. FOOD & DRUG**  
ADMINISTRATION