

Foreign-invested pharmaceuticals corporation registration in China

Application requirements(conditions):

- The minimum registered capital:500,000RMB
- have practical registered address, the premise for business
- shall comply with the national and local statues and the foreign-invested industry policy.
- shall comply with the national economic and social development long-term planning, industrial planning, structure adjustment policies .
- shall comply with the public interest and the relevant provisions of the anti-monopoly
- shall comply with land-use planning, the overall urban planning and environmental protection policy requirements
- shall meet the states requirements of technical、arts and craft standard
- shall comply with the relevant provisions of state capital project management and the external debt management
- did not affect the city?economic and social security
- shall comply with foreign investment projects is a national restricted industries, shall provide inspectional advices of the industry sector

Application procedure and documents:

1. pre-approval of name of WFOE Examination and Approval Department:

Administration of Industry and Commerce

Time limit:

Within 2 working days

Required documents:

Pre-approval for names of enterprise
Appointment letter

2. Application for setting up WFOE Examination and Approval Department:

State Development and Reform Commission

Time limit:

Within 20 working days

Required documents:

Application for project report

Identification of foreign investor (1、opening certificate、Identification of legal representative if the investor is a corporation ,including list of member of investor?shareholders、 list of member of board of directors、 resolution of represent authorized by the board of directors
2、 copy of ID, if the investor is a person. The qualification certificate and identification shall be notarized by the national notary institution and authorized by the host country's embassy (consulate))

Credit certificate of investor (issued by the bank)

Investment letter of intent

Other documents complied with the national and local statues and the foreign-invested industry policy.

3. the environmental assessment for establishment of enterprises Examination and Approval Department:

State Environmental Protection Administration

Time limit:

30 working days after acceptance

Required documents:

The registration form for application of construction projects environmental management Construction Project Environmental Impact registration form or construction project environmental impact reports (written), includes:

The preparation of environmental impact reports (written) are required to provide one written document and one electronic file

Project involves the construction of water and soil conservation, water also must have the Soil and Water Conservation Program the consented by the executive department

Environmental impact reports (written) shall meet demands of "on further standardize the work of the environmental impact assessment notice" (Central Office [2002] No. 88)

Project proposals and one approval document by relevant authorities (In accordance with relevant state regulations do not need to conduct a feasibility study , can be submitted only building project description)

Construction projects needed pre-trial by the industry sector in accordance with the law, shall hold the pre-trial opinion

Enterprise names pre-approved noticesM

Copies of certificates of title

Enterprises location map

Business establishments?floor plan.

State Development and Reform Commission

if the environment may cause significant impact and need to prepare environmental impact report and in accordance with the requirements construction projects which need to seek the views of residents around construction projects, are required to provide the results of verification meetings, hearings or other means to seek relevant units, experts of public opinion, but except confidentiality in accordance with the provisions.

4. GMP Certification Examination and Approval Department:

The province State Drug Administration or above

Time limit:

State Environmental Protection Administration begin to approval procedure within 6 months

GMP certification procedures:

Article 1: enactment of this procedure in accordance with the spirit of other relevant documents notice State Drug Administration issued such as "Drugs GMP authentication management practices," enactment of this notification procedures.

Article II: Drug Administration is in charge of first-trial of application certification applied by GMP pharmaceutical production enterprises and gain "Drugs GMP certificate" and (workshop) day-to-day supervision and inspection work of enterprises (workshop).

Article 3: In the administrative area, offered by pharmaceutical production enterprises, including various forms of joint ventures, Sino-foreign cooperative business, Chinese-foreign joint ventures and WOFE, must comply with the procedural requirements.

Required documents:

"Drugs GMP certification applications" in duplicate,

"Pharmaceutical manufacturer's license" and "business license" (photocopy);

Self-examination situation of Drug production management and quality management (including corporate overview and historical evolution of the situation, production and quality, correction situation of the previous certification defects project);

Production organization chart of Pharmaceutical production enterprises (workshop) (specify the name of every organizations department, their mutual relations, department heads) photocopy of the resume \ certificate qualifications and titles of the legal representative, statutory agents, the responsible persons, head ; registration form of pharmacy and related professional and technical personnel, engineering technicians, skilled workers in accordance with the law and marked with the host departments and position; ratio form of High, intermediate and early the technical personnel.

Pharmaceuticals production enterprises surroundings map, the layout map, quality testing sites layout diagram;

General and pharmaceutical production plant layout of the floor plan (including changing rooms, toilet, and material flow channel, gas gate, and marked the air cleaner grade); The layout diagram of air supply air purification system, return air, exhaust Process equipment dosage forms of application for certification or process diagram, indicate the main point of process control and control projects;

situations about the key processes of pharmaceuticals production enterprises (workshop), major equipment, water systems and air purification system certification and testing instruments, meters, weighing instrument calibration;

document directory of production management, quality management of pharmaceuticals production enterprises (workshop),;

new pharmaceutical production run enterprises (workshop) for GMP certification, in addition to submit the documents specified in Article 5, submitted the copy of the batch production records certification scope related the variation

5. Production licenses for drugs and medicines business license Examination and Approval Department:

State Drug Administration

Time limit:

Within 30 working days

Required documents:

Registration form of Drugs production license
The basic situation of the applicant and its related documents
The basic situation of enterprises
Notice of Pre-approval for names of enterprise
The proposed organization chart of enterprises
photocopy of the resume , certificate qualifications and titles of the legal representative, statutory agents, the responsible persons, head ; registration form of pharmacy and related professional and technical personnel, engineering technicians, skilled workers in accordance with the law and marked with the host departments and position; ratio form of High, intermediate and early the technical personnel.
Surrounding environment map, general layout plans, storage layout map, quality testing sites layout map of enterprises
The proposed layout of the floor plan in enterprise production process, the air supply air purification system, return air, exhaust layout diagram, process equipment layout plans
To produce varieties based on the quality standards and Formulations or varieties to the production process flow diagram, and indicate key points and project quality control
Major equipment and system verification profiles; the production, testing equipment, instruments, weighing instrument calibration
The main production equipment and testing equipment directory
The document directory of proposed enterprise production management, quality management,
Instrument of commitment of application materials authenticity of a statement of self-assurance, and materials to bear the legal responsibility
Authorized instructions

6. Application for setting up WFOE Examination and Approval Department:

Municipal bureau of commerce

Time limit:

Within 7 working days

Required document:

Application for setting up WFOE

Feasibility report
Article of association
Appointment letter of member of board of directors
Identification of member of board of directors
List of member of board of directors
Identification of foreign investor (1、 opening certificate、 Identification of legal representative if the investor is a corporation, including list of member of investor?shareholders、 list of member of board of directors、 resolution of represent authorized by the board of directors
2、 copy of IC, if the investor is a person. The qualification certificate and identification shall be notarized by the national notary institution and authorized by the host country's embassy (consulate))
Credit certificate of investor (issued by the bank)
Proof of the use of premises (including rental contract, proof of premises)
Notice for pre-approval name
Letter of Authorization for legal documents service
Instrument of commitment
The copies of the IC and the power of attorney of the personnel

7. To process proposed agency code Examination and Approval Department:

State Bureau of Technical Supervision (The Administration Center of Organization Code)

Time limit:

2 working days after acceptance

Required documents:

Approval of article of association

Application of proposed agency code

8. Industry and Commerce registrations of WFOE Examination and Approval Department:

Administration of Industry and Commerce

Time limit:

7 working days

Required document:

Application form of setting up WFOE

Article of association

Approval by the approving authority and the copy of《Approval letter of foreign-invested enterprise》

Identification of foreign investor (the qualification certificate and identification shall be notarized by the national notary institution and authorized by the host country's embassy (consulate))

Credit certification of investor (issued by the bank)

Notice for pre-approval name of the enterprise, name list of the pre-approval investor

Letter of Authorization

Corporate secretary (contact) registration form

Letter of Authorization for legal documents service

Besides, the printed name list of the investor, member of the board of director, general manager and supervisor, one copies each.

9. To record in Public Security Bureau Examination and Approval Department:

Municipal Public Security Bureau (the administration center of embarkation and disembarkation)

Time limit:

6 working days

Required documents:

The registration application for record

The identification of legal representative

Business license, approval letter, photocopy of approval

10. To engrave of chop of enterprise Examination and Approval Department

Engrave of chop organization proposed by police station

Time limit:

2 working days

Required document:

Application form of chop engrave

11. Apply code of enterprise Examination and Approval Department:

State Bureau of Technical Supervision (The Administration Center of Organization Code)

Time limit:

3 working days after acceptance

Required materials:

Application form
Returning paper of proposed agency code
The identification of legal applicant
Business license, approval letter, photocopy of approval

**12. Tax registration
Examination and Approval Department:**

Municipal Local Taxation Bureau

Time limit:

5 working days

Required document:

Identification of legal representative
Business license, approval letter, photocopy of approval
Housing contract
Registration form of tax

**13. Registration of administration of foreign exchange
Examination and approval department:**

center of foreign exchange control

Time limit for handing:

20 working days after acceptance

Required materials:

Written application (stamped by chop)
Copy of business license provided by the legal representative, non-legal representative enterprise shall provide original and photocopy of business license
Approval documents for approving the setting up of enterprise issued by the Commerce Department, the original and photocopy of the certificate.
Effective contract of foreign-invested enterprise (except for wholly-owned foreign enterprise), original article of association and its photocopy.
Original and photocopy of code of enterprise

14. Opening bank account

Due to the different requirement of the bank, the required documents need to be confirmed.

15. Financial registration Examination and Approval Department:

The financial bureau

Time limit for handling

2 working days after acceptance

Required materials:

Business license, approval certificate, photocopy of approval
Financial registration form

16. Statistic registration Examination and Approval Department:

The statistical bureau

Time limit for handling

2 working days after acceptance

Required materials:

Copy of Business license, approval certificate, photocopy of approval
Statistic registration form

17. Customs procedure to register WFOE Examination and Approval Department:

Customs

Time limit

within 5 working day

Required documents:

Copy of Business license
Approval certificate, photocopy of approval

Photocopy of article of association photocopy.
Photocopy of tax registration
Photocopy of bank account certificate
Photocopy of certificate of proposed agency code
moulage of chop of enterprise, juridical person and apply to customs
Registration form for apply customs
Registration form of management for apply customs