Shanghai Food and Drug Administration Issues Regulation for Domestic Processing and Manufacturing of Foreign Pharmaceutical Companies

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Following the State Food and Drug Administration (FDA)'s notice,"Enhancing Regulations for Domestic Processing and Manufacturing for Foreign Pharmaceutical Companies" (translation available upon request), the Shanghai FDA enacted its own regulations for Shanghai contract manufacturers of foreign pharmaceutical companies to ensure pharmaceuticals that are contract manufactured in China meet the drug standards of the United States.This is a cross-border regulatory cooperation between Chinese and American governmental authorities. Concerned U.S. companies are encouraged to read through and leverage the regulations that would be beneficial to them.

Following the State Food and Drug Administration (FDA) Notice, "Enhancing Regulations for Domestic Processing and Manufacturing for Foreign Pharmaceutical Companies", (State Food and Drug Safety [2011] 325), the Shanghai FDA enacted the following regulations for Shanghai contract manufacturers of foreign pharmaceutical companies.

Strengthen Management and Regulation of the Contract Manufacturing for Foreign Pharmaceutical Companies

(A) Requirements on the Foreign Pharmaceutical Company (the Principal)
The Principal must be a foreign pharmaceutical company, and the pharmaceutical drug being manufactured must have the proper overseas license for sale. The contract between the domestic manufacturer must be directly with the Principal.

(B) Requirements for the Contract Manufacturing Agreement (the Contract)
1. The Contract should specify the rights and obligations of each party, and clearly state the Principal is responsible for the safe quality of the manufactured pharmaceutical drug.

2. The Contract should include a technical provision clearly describing the production process and quality standards.

(C) Strengthen regulations on the authenticity and legality of the overseas license for sale of the manufactured pharmaceutical drug

The Contract Manufacturer shall strengthen its due diligence with regard to the proper qualifications and foreign license of the manufactured pharmaceutical drug, with all relevant license materials clearly documented. If the Shanghai FDA has any concerns regarding the foreign license, the Contract Manufacturer shall work with the Shanghai FDA to provide the relevant license certification documents.

(D) Strengthening regulations for labelling of manufactured pharmaceutical drug

The Contract Manufacturer shall print its name and address on either the exterior label or the instruction booklet. However, it should not print on the label the domestic pharmaceutical drug registration number, the import drug registration number and the recordal number for contract manufacturing.

(E) Strengthening packing requirements for manufactured pharmaceutical drug

The Contract Manufacturer may not manufacturer pharmaceutical drug without packaging.

(F) Strengthen the management and regulation of processing for the foreign pharmaceutical drug

1. The Contract Manufacturer should establish detailed processing and quality control procedures, and record all relevant data related to the entire manufacturing process.

2. The Contract Manufacturer should be in strict compliance with the strict contract manufacturing process, quality standards and “Good Manufacturing Practice” at the filing location for production processing.

3. The Contract Manufacturer should faithfully record the material procurement and production, and quality inspection of the entire process to ensure quality traceability, and save all records in accordance with sound pharmaceutical production and quality control. These records must be maintained by the Contract Manufacturer for at least one year after the expiration date of the pharmaceutical drug.

4. The Contract Manufacturer should save samples for each manufactured batch to prepare for the necessary inspection or testing.

5. The Contract Manufacturer shall report to the local Food and Drug Administration quarterly quality production reports. Should there be any anomaly detected within the manufacturing process, the local FDA should be notified immediately.

Contract Manufacturer should Conduct Self-Examination and Examination of the Principal

The relevant pharmaceutical companies shall further strengthen their management and fill out the "Shanghai Contract Pharmaceutical Manufacturers of Foreign Pharmaceutical Checklist" form and submit it to the relevant county FDA and the department of Drug Safety of the Shanghai FDA by September 10, 2011.

Strengthen Supervision and Regulation of Contract Manufacturer in the Local Jurisdiction Area

The county FDA shall, together with its annual review of pharmaceutical manufacturing companies, strengthen the supervision of contract manufacturers for foreign pharmaceutical drug companies.

The Shanghai FDA shall, in accordance with the local county FDAs, perform targeted inspections of contract manufacturers for foreign pharmaceutical drug companies. The contract manufacturers found to have incorrect records, concealment of contract processing, lack of due diligence for self-examination, lack of proper registration or falsified records will be severely dealt with according to relevant laws and regulations. Those cases that constitute a serious crime will be transferred to the local prosecutor for criminal prosecution.

Potential Implications

These regulations enhance the Shanghai FDA's supervision for contract manufacturers of foreign pharmaceutical companies. For foreign pharmaceutical companies seeking to contract manufacture in China, it is import to note that they are the final party responsible for any safety

or quality issues regarding the contract manufactured pharmaceutical drug. For domestic contract manufacturers, they are subject to rigorous reporting and self-examination obligations.

In addition, the Shanghai contract manufacturer must fill out the comprehensive form on their contract manufacturing activities and submit to the relevant authorities by the September deadline. Subject to the Notice, contract manufacturers for foreign pharmaceutical companies should expect inspections and careful supervision of their activities in the near future.