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E-ALERT | Food & Drug

December 2, 2013

CFDA RELEASES NEW PROPOSED RULE ON DRUG CONTRACT MANUFACTURING FOR PUBLIC COMMENT

The China Food and Drug Administration ("CFDA") recently published a proposed rule regarding the management of the examination and approval of applications for drug (including biologic) contract manufacturing arrangements ("proposed rule") between drug manufacturers located in China. The term "contract manufacturing of drugs," as it is used in the proposed rule, refers to an arrangement in which a licensed drug manufacturer in China that has obtained approval to manufacture a specific drug entrusts the manufacturing of that drug to another domestic drug manufacturer. In China, these arrangements must be approved by CFDA or a provincial level FDA (PFDA) and can last up to two years, with the option of applying for extensions. The proposed rule addresses issues involving regulatory jurisdiction of the provinces, application procedures, inspections, and penalties relating to contract manufacturing of drugs in China.

CFDA invites interested stakeholders to submit comments by December 8, 2013. Foreign and Chinese companies that manufacture drugs or biologics in China should closely monitor developments associated with this rule, as it may affect their existing arrangements.

Contract manufacturing of drugs is not a new arrangement in China. The Drug Administration Law permits contract manufacturing arrangements. In 2004, CFDA promulgated its Measures on the Supervision of Drug Manufacturing (the "Measures"), which set forth detailed requirements for companies to structure their arrangements and to submit their contract manufacturing applications, which are separate from their new drug applications, to CFDA or a PFDA for approval. Under the Measures, CFDA must approve contract manufacturing arrangements for intravenous drugs and biologics (excluding vaccines and blood products), as well as arrangements in which the two parties are located in separate provinces. All other arrangements must be approved by PFDAs.

The proposed rule marks a departure from the Measures in a few ways. First, for situations in which the two parties are located in separate provinces, CFDA would no longer be required to approve the arrangement. Instead, the PFDA located in the same province as the party contracting out the manufacturing must make the ultimate decision approving the arrangement. The PFDA in the other province may issue an "opinion" on the arrangement. When two provinces are involved, that inspection will be conducted jointly by the PFDAs of the two relevant provinces. Previously, these cross-provincial arrangements were coordinated by CFDA.

In addition, the proposed rule would prohibit contract manufacturing arrangements for certain types of products. Specifically, the proposed rule would prohibit contract manufacturing of, *inter alia*, narcotic drugs, psychoactive drugs, pharmaceutical precursor chemicals and finished drug products containing pharmaceutical precursor chemicals, biochemical drugs with multiple ingredients, and biologics. The Measures did not contain similar prohibitions against contract manufacturing arrangements for these drugs and biologics. The proposed rule authorizes CFDA to adjust these prohibited categories as it sees fit. The proposed rule states that it shall supersede any conflicting

provisions in pre-existing CFDA rules. Therefore, if the proposed rule is adopted, it would control over certain provisions in the Measures.

The proposed rule appears to focus on streamlining the management of the review and approval of applications for contract manufacturing. It has not changed the existing "bundling system," under which the approval to manufacture a drug in China is issued (bundled) only to a company that has GMP-certified manufacturing facilities. As a result, a small research and development (R&D) company located in China without commercial manufacturing capabilities will still not be able to obtain approval to manufacture the drug it has developed and then contract out the manufacturing activities to another company that has commercial manufacturing capabilities. The small R&D company will still need to follow the "technology transfer" pathway, rather than the "contract manufacturing" pathway, in order to have the manufacturing activities undertaken by a separate commercial manufacturer.

Drug manufacturers in China, particularly those with cross-provincial contracting arrangements, should pay close attention to the development of the proposed rule.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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