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ALERT

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# China FDA Solicits Comments on Resolving the Backlog of Drug Applications

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The China Food and Drug Administration ("CFDA") recently published a draft circular to address the backlog of drug applications. The *Circular Regarding Several Draft Policy Opinions to Accelerate the Resolution of the Backlog of Drug Applications Issued by the CFDA* (CFDA Circular [2015] No. 140, the "No. 140 Circular"), which is open for public comment through August 15, 2015, proposes ten policies to reduce the backlog of the drug applications and expedite the approval process for certain types of drugs. The No. 140 Circular also proposes changing the approval system for bioequivalence studies.

The No. 140 Circular appears to be a response to the State Council's criticism of the CFDA earlier this summer. In May and June, the State Council conducted a nationwide review regarding the implementation of significant policies. According to the resulting summary report, nine departments (including the CFDA) were criticized and ordered to conduct rectifications within a specific time. Specifically, the main criticism of the CFDA was that its drug review and approval process was inefficient. The CFDA's first response to this criticism came with its circular regarding the commencement of a self-inspection project for drug clinical trial data. Published on July 22, 2015, this *Circular Regarding the Launch of Self-Inspection of Drug Clinical Trial Data* (CFDA Circular [2015] No. 117, the "No. 117 Circular") requested that the applicants of 1622 drug submissions submit a self-inspection report to the Center for Food and Drug Inspection of CFDA. The No. 117 Circular further provided that, if the self inspection revealed inaccurate or incomplete clinical study data, the applicant should withdraw the application voluntarily by August 25, 2015.

The CFDA's latest response to the State Council's criticism has taken the form of the No. 140 Circular, which provides the following implementation rules:

- **Raises the technical review standards for generic drugs**: If the originator drug has been marketed in China, generic applications will be approved only if their quality and efficacy is consistent with that of the originator; if the originator has not yet marketed in China, any approved generic drugs must pass a consistency evaluation within three years after going to market in China. If the generic drug fails to pass the consistency evaluation within the three years, the corresponding drug approval will be revoked.
- **Imposes severe penalties on false data submitted in drug applications**: If any false data is found in the clinical trial, the relevant authority will blacklist the relevant applicant, clinical trial site, contract research organization or the relevant responsible person. In addition, such applicant will be debarred from drug applications for three years, and such responsible person will be debarred from participating drug clinical materials for ten years.
- **Rejects drug applications that fail to meet requirements**: The No. 140 Circular reiterates that applicants must complete the self-inspection in accordance with the No. 117 Circular by August 25, 2015. An applicant can withdraw its applications voluntarily if it finds any major defects during the self-inspection. Meanwhile, the CFDA can disapprove the application directly if it finds any major defects during the technical review process.
- **Strictly controls the approval of drug applications for changes in dosage form, acid or alkaline forms, or route of administration**: Applicants seeking approval for such changes must present evidence

of innovation, safety and efficacy, and thus an obvious advantage when compared with the original dosage form. Proposed changes that do not present such obvious advantages will not be approved by the CFDA.

- **Optimizes the review and approval for clinical trial applications**: The review of clinical trial and bioequivalence study applications will focus on the measures to assure the subjects' safety. The CFDA will disapprove any application with major defects. If no major defects are found, the CFDA can issue a conditional approval, with the applicant making any necessary improvements in its research plan based on the technical guideline. Bioequivalence studies will no longer require affirmative prior approval and will instead only require notification to the CFDA. If the CFDA raises no objection within thirty days from the applicant's notification, the applicant may initiate the bioequivalence study.
- **Launches centralized review of the same type of drug applications in the backlog**: For drug applications of the same type accepted by the authorities, the CFDA will launch a centralized review based on the same review criteria.
- **Accelerates the approval process for drugs that address urgent clinical needs**: Pediatric drug applications, as well as drug applications that have been submitted by the drug administrations in the EU and the US simultaneously, will be subject to fast track approval. Furthermore, the National Health Family Planning Commission and the Ministry of Industry and Information Technology will propose a list of drugs for which there is an urgent clinical need or shortage. The CFDA will then provide additional comments regarding the eligibility of fast track approvals for such drugs to seek approvals from the State Council.
- **Addresses pending applications from the 2008 centralized review**: Any applications still pending from the 2008 centralized review will be returned to the applicants if the applicants cannot resolve the issues regarding safety, efficiency, quality control, or authenticity of the research materials.
- **Discourage generic companies from redundant applications**. The CFDA will compile a Catalogue of Generic Drugs subject to Restricted Review and Approval. This Catalogue will serve as guidance to streamline generic applications. Generics whose supplies are greater than demand, which have an unclear therapeutic effect or safety profile, or whose formulations are insensible will be placed on the Catalogue.
- **Regulates the drug registration appeal procedure**: If the applicant disagrees with the CDE's technical review decision, it can submit an appeal application. Thereafter, the CDE will invite experts, the applicant, and the technical review officials to a technical review meeting and the relevant technical appeal conclusion will be published to the public.

In summary, the release of the No. 117 Circular and the No. 140 Circular are believed to be CFDA's proposed rectification scheme that will be submitted to the State Council to address the drug application backlog issue and thus improve the efficiency of the drug review system. Companies who have pending drug applications in China are advised to review their pending drug dossiers and pay close attention to such policies.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.