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E-ALERT | Food & Drug

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CHINA ISSUES SECOND PROPOSED DRAFT OF PRIMARY DRUG REGULATION

On February 20, 2014, the China Food and Drug Administration (CFDA) released a second proposed draft of revisions to the Drug Registration Regulation (second draft DRR). As we noted in our prior alert (here) on the first draft of revisions to the DRR (first draft DRR), the DRR is the primary CFDA regulation for seeking approval of clinical trials and for bringing innovative and generic drugs and biologics to the market in China. The revision of the DRR comes at an important time, because China also plans to revise its primary drug regulatory statute, the Drug Administration Law (DAL), at some point in the next few years. Any revisions to the DRR could have a significant impact on the consideration of amendments to the DAL.

For the first draft DRR, CFDA released several legislative materials, including a chart comparing the revisions with the current DRR and a drafting explanation. CFDA is required, pursuant to its own legislative rules, to release a drafting explanation with the proposed rules it releases for notice and comment. However, with the second draft DRR, CFDA has only released the draft text, with no comparison chart and no explanation as to the changes it made between drafts. Comments on the second draft DRR are due on March 23, 2014.

Very little has changed between the two drafts. In the second draft DRR, CFDA has not expanded its revisions to additional areas. It has, with one exception, only made minor changes to the proposed text. As we noted in our prior alert, the primary revisions in the first draft were:

- Permitting applications for generic drug registration to be filed at any time prior to the expiration of the patent term.
- Permitting certain amendments to approved clinical trial applications. Specifically, applicants may file a supplement—along with supporting documents and research—to account for either a necessary adjustment to the applicant, or changes to the manufacturing process, formulation, or specifications of the product, or a change to the manufacturing sites. Other than changes to the applicant, changes must take place before a Phase III clinical trial has been initiated.
- Expanding the new drug monitoring period to include those who have had their clinical trial applications accepted for filing, as opposed to approved, by CFDA at the time that the new monitoring period commences.
- Permitting clinical trial applications that have been accepted for filing to proceed to approval once an imported drug is approved for the first time in China.
- Requiring certification of compliance with Good Laboratory Practices for institutions conducting preclinical safety assessments.
- Conducting facility inspections of generic manufacturers after the clinical trial or bioequivalence study is completed.

The above described revisions remain substantially the same in the second draft DRR. More detail on them is provided in our prior alert.

CHANGES TO THE REVISIONS RELATED TO PATENT PROTECTION

The major difference between the two drafts is in the area of patent protection. Currently, Article 19 of the DRR (a) prevents generic manufacturers from submitting applications to register generic drugs until two years prior to the end of the patent term of any originator patents claiming the drug, and (b) prevents CFDA from approving any application for a generic drug until the expiry of any such patents. The first draft DRR proposed to delete Article 19 in its entirety. The second draft DRR, however, modifies Article 19, thus preserving more of a role for CFDA in protecting originator patent rights.

By deleting Article 19 altogether, the first draft DRR would have permitted generic manufacturers to submit generic drug applications at any time, without regard to the status of originator patents. The drafters explained that this change was intended to reduce tension with China's Bolar (or research) Exemption under the Patent Law. The deletion of Article 19 also would likely have meant that CFDA could issue marketing licenses prior to the expiration of originator patents. Thus, generic manufacturers would have been free to market potentially infringing generic drugs until the originator manufacturers succeeded in enforcing their patents.

The second draft DRR takes a slightly different approach. Like the first draft DRR, the second draft DRR deletes Article 19's limitation on submitting generic drug applications two years prior to the expiry of originator patent terms, thus allowing generic applications to be filed at any time. With respect to the prohibition against CFDA approval of generic applications until after originator patent term expiry, the second draft DRR revises this provision, rather than deleting it. Under the second draft DRR, it appears that CFDA may issue a license for a generic drug while a patent exists. However, the new text states that the generic drug license will not become effective until after the expiry of the originator manufacturer's patent(s). This is not unlike the "tentative approval" mechanism that exists for generic drug applications in the United States

The second draft DRR is more favorable to originator manufacturers in this respect than the first, because it arguably prevents final approval of generic drug applications until after the expiration of originator patents. In addition, compared with the first draft, it preserves at least some role for CFDA in protecting patent rights. However, it is not clear what CFDA will do to enforce this new text, or what action an originator manufacturer could take to enforce its rights. It is not clear whether the originator manufacturer will have to offer a successful judgment in a patent case in order for the newly issued generic license to be deemed ineffective. It is also not clear whether the originator will be notified of the filing of the generic drug application so the originator can start a patent lawsuit.

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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