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CFDA PUBLISHES DRAFT RULE ON ADMINISTRATIVE PROCEDURE FOR PUBLIC COMMENT

As discussed in a previous client alert, the Chinese Food and Drug Administration (CFDA) underwent an internal reorganization in March of this year. Additionally, as part of the March reforms, CFDA is no longer part of the Ministry of Health and now itself holds the rank of a ministry. This change enhances CFDA's power to promulgate its own rules. Since that time, the agency has begun to revise or add to its existing rules on food, dietary supplements, drugs, devices, and cosmetics. CFDA has also endeavored to make its regulatory practices, both in terms of rulemaking and the enforcement actions that it takes, more transparent and responsive to the public.

As part of its efforts in the rulemaking area, CFDA recently issued a proposed rule (Draft Rule) that revises its 2002 Provisions on Legislative Procedures (2002 Provisions). The 2002 Provisions set forth requirements for drafting, enacting, interpreting, and canceling the agency's own rules or other legislation that it drafts with other agencies or for the State Council. The 2002 Provisions function, in many ways, like an administrative procedure act for CFDA. These Provisions are important for understanding how the agency makes its policy and how stakeholders can submit their views to the agency during that process. The Draft Rule sets out new ways for stakeholders to understand and participate in CFDA rulemaking. For example, the Draft Rule allows stakeholders to participate not just through opportunities for notice and comment, but also through proposed new areas for rulemaking. For these reasons, life sciences companies with products regulated by CFDA in China should consider submitting comments and should closely monitor the development of the Draft Rule. The agency will accept public comments on the Draft Rule through September 5, 2013.

The Draft Rule adds new procedures on rulemaking, while also strengthening existing procedures. Some of the more significant features are as follows:

- **Citizen proposals of legislative items.** In the section of the Draft Rule on setting a rulemaking agenda, a new provision adds a procedure through which the public may submit proposals for laws, regulations, and rules "that relate to food and drug regulation." The public can submit these proposals directly to CFDA via letter, online, or through various other channels.
- **A stronger role for stakeholder participation.** In recent years, the Chinese government has taken strides to make its rulemaking procedures more transparent. CFDA consistently releases draft rules and guidance documents and provides approximately 15 to 30 days for public comment. The Draft Rule maintains the channels for stakeholder participation that the 2002 predecessor rule included – such as roundtable discussions, seminars, hearings, field research, and online forums – but makes the requirement of opportunity for notice and comment explicit. For example, the Draft Rule states that the drafters "shall" solicit a broad range of comments in the drafting process from "other agencies, organizations, industry associations, grassroots law enforcement officials, and the public." In addition, it now requires that a "drafting explanation" be included in any proposed draft released to the public to explain opinions from the public and other relevant opinions and "the circumstances of their inclusion." The Draft Rule, however, does not clearly require the inclusion of a "final rule explanation" to accompany the final rule to

explain how the agency responds to any public comments submitted in response to the Draft Rule.

- **Emphasis on legislative research.** The Draft Rule places greater emphasis on the importance of drafting practical regulations through in-depth research. As part of the rulemaking process, drafters must engage in thorough research of the current regulatory problem, the regulatory history, and other prior experience dealing with the issue both in China and overseas. The drafters must also conduct social and economic risk assessments, if the rule will represent a significant regulatory change or will have a significant impact on the rights of a group of people or on the development of the food and drug industry. These risk assessments result in a cost-benefit analysis, analogous to that performed in the US. These types of risk assessments are becoming a more prominent feature of administrative process in China.
- **Procedures for enacting CFDA guidance.** CFDA promulgates rules and guidance documents, the latter of which are part of a general class of quasi-legislation in China called "normative documents." Rules have higher authority than normative documents. Many agencies and local governments have engaged in efforts to regulate the enactment of normative documents more stringently to ensure that they do not conflict with other legislation or impose arbitrary requirements on stakeholders. The Draft Rule includes provisions addressing normative documents, which for the first time the Draft Rule recognizes explicitly as having general binding force on stakeholders. This change should clear up any doubts about the binding nature of normative documents that existed before. The Draft Rule states that some of the basic procedures governing the drafting of administrative rules apply to the development of normative documents. It also requires CFDA to publish lists of canceled normative documents to avoid confusion. These changes to the normative document drafting process will hopefully lead to clearer, more user-friendly guidance documents that do not conflict with other guidance documents or rules.
- **Special procedure for rules affecting foreign entities.** The Draft Rule also adds a new provision requiring CFDA to consult the State Council prior to the promulgation of any regulation or guidance document that CFDA issues if it involves a change of China's foreign policy or specifically regulates foreign businesses in China.

Overall, the Draft Rule is evidence of efforts to reform both CFDA itself and the substantive content of food, drug, device, and cosmetics law and regulation in China. The Draft Rule also reflects the influence of broader trends in administrative regulation in China, such as increased transparency, stakeholder participation, and reform of inter-agency relations. Once CFDA receives comments, it will consider them and may revise the Draft Rule. There is no deadline for the Draft Rule's promulgation.

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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