COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Food & Drug

April 8, 2014

CFDA ANNOUNCES FIVE RECTIFICATIONS CAMPAIGN TARGETING MEDICAL DEVICES

On March 13, 2014, the China Food and Drug Administration (CFDA) announced a special five-month campaign targeting five areas of medical device enforcement. Those five areas are medical device registration, manufacturing, distribution, promotion and use in healthcare institutions ("Five Rectifications Campaign"). The campaign began on March 15, 2014 and will end on August 15, 2014. CFDA has published an action plan describing the Five Rectifications Campaign, along with an explanation of the plan.

Areas of Focus

In the action plan and the explanation, CFDA sets forth specific and narrowly targeted areas that the campaign will focus on:

1. False Information in Registration Applications

The focus in this area will be on false information submitted in applications for the initial registration of Class II and Class III medical devices (which require additional regulatory oversight to ensure safety and effectiveness). The plan specifically targets false clinical trial reports and the authenticity of the sample production process.

2. Illegal Manufacturing

This area will primarily focus on the use of raw and semi-finished materials that do not meet relevant standards for manufacture of disposable infusion/injection instruments and disposable catheters, as well as the improper sterilization of those devices. The illegal manufacturing part of the plan will also focus on the unauthorized contract manufacturing of condoms and the release of hemodialysis concentrate that does not meet relevant standards.

3. Illegal Distribution

The plan focuses on problems with distribution of unregistered Class II and III devices via experiential marketing (i.e., by supplying user samples), unregistered colored contact lenses and hearing aids, and in vitro diagnostic reagents that have not been stored or transported in accordance with relevant standards and regulations.

4. Exaggerated Promotional Claims

The plan focuses on exaggerated therapeutic claims for products for back or leg pain, nearsightedness, diabetes, hypertension, and physiotherapeutic products; exaggerated product indications and efficacy claims in unapproved advertisements; and illegal endorsements by research organizations, technical experts and patients. Though not stated explicitly, the focus appears to be on advertisements, as opposed to promotional oral statements, as the stated method of

enforcement is referral to the State Administration For Industry & Commerce and possible revocation of advertisement approval among other penalties.

5. Use of Unregistered Devices

The plan also proposes to increase enforcement against the use of unregistered in vitro diagnostic reagents by medical institutions. This mandate comes very soon after CFDA issued a notice requiring that all unlicensed human genome-sequencing instruments, re-agents, and software used for the prevention, diagnosis, and treatment of disease register as medical devices and that all healthcare institutions scrutinize the use of such reagents and instruments.

Enforcement

According to the action plan, CFDA and provincial food and drug regulatory authorities will engage experts and media to investigate and report to CFDA on the critical areas of focus described above. That information, along with sample testing conducted by CFDA, will be used to compile a list of companies and products for targeted inspection. The provincial food and drug regulatory authorities will then use the list to conduct unannounced inspections and investigate any violations found therein.

The action plan and explanation also specify that related violations discovered in the course of the Five Rectifications Campaign will be punished by the maximum penalty allowed by law. For egregious cases, CFDA will revoke medical device registrations and licenses to operate, such as medical device manufacturing and distribution licenses. CFDA will also order recalls of unsafe devices and refer any suspected criminal cases to the public security bureau for criminal investigation and prosecution.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

Shaoyu Chen	86.10.5910.0509	schen@cov.com
Scott Cunningham	415.591.7089	scunningham@cov.com
John Balzano	212.841.1094	jbalzano@cov.com
Nan Lou	202.662.5097	nlou@cov.com