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E-ALERT | China Life Sciences Practice

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SFDA ISSUES DRAFT REGULATIONS FOR BLACKLISTING VIOLATORS OF CERTAIN DRUG OR DEVICE LAWS

On May 30, 2012, China's State Food and Drug Administration ("SFDA") issued draft regulations entitled *Provisions on the Administration of a Drug Safety Blacklist* ("Proposed Provisions") for public comment. If adopted, the Proposed Provisions would require SFDA to maintain a blacklist of companies and individuals directly responsible for certain serious violations of drug or medical device laws and regulations. Blacklisted companies or individuals may be denied administrative permits and subjected to close SFDA monitoring and inspection. This blacklist would be published and updated periodically on SFDA's website and circulated to many government agencies. The formal comment period for the Proposed Provisions ended on June 6, 2012.

Through this "naming and shaming" mechanism, SFDA intends to deter violations and increase enforcement activities against companies or individuals that have violated certain key laws and regulations. Companies and individuals engaged in the research, development, manufacturing, and distribution of drugs or devices in China need to be aware of the serious implications of the proposed blacklist and diligently comply with SFDA regulations in order to mitigate corporate or individual liability and business interruption.

WHO WILL BE BLACKLISTED?

Article 7 of the Proposed Provisions requires SFDA to blacklist companies or individuals engaged in the following activities:

1. producing or selling counterfeit or inferior drugs, where the violation is serious;
2. producing unregistered devices or devices that substantially fail to meet national or industry standards;
3. concealing relevant information or submitting false information when applying for an administrative permit;
4. obtaining an administrative permit through false certificates, documents, or samples, or through other improper methods, such as fraud or bribery;
5. violating GMPs or other legal requirements on production and distribution of drugs or devices, resulting in serious safety incidents;
6. forging, intentionally destroying, or concealing evidence, or otherwise obstructing SFDA investigations;
7. being criminally penalized due to violations of drug or device laws and regulations; and
8. other violations of drug or device laws and regulations, when the violations are intentional, egregious, and result in serious harm.

SFDA must also include on the blacklist individuals who have previously received a 10-year prohibition from producing or distributing drugs and devices due to serious violations relating to producing or selling counterfeit or inferior drugs.

WHAT ARE THE PENALTIES?

In addition to posting on the blacklist, the Proposed Provisions also specify new penalties for certain of the violations listed above. These new penalties include:

- A rejection of the application and a one-year prohibition against applying for administrative permits for a company or an individual that conceals relevant information or submits false information in an application for an administrative permit. If the application is for clinical trial, the prohibition is currently three years under existing drug laws and regulations.
- A revocation of any permit obtained — and a three-year prohibition against filing for the same type of permit — for obtaining an administrative permit through false certificates or documents, fraud, or bribery. The prohibition is currently five years under existing drug laws and regulations for improperly obtaining a drug manufacturing or distribution permit.
- A 10-year prohibition against a drug manufacturer or distributor employing an individual responsible for "producing unregistered devices or devices that substantially fail to meet national or industry standards."

HOW DOES THE BLACKLIST WORK?

- Within 15 working days after a company or an individual receives an administrative penalty related to one of the offenses listed above, SFDA will add the name of the penalized company or individual to the blacklist on the SFDA website.
- Provincial food and drug administrations will add the name of a penalized company or individual to the blacklists that they maintain on their websites and also submit the information to the SFDA for posting on the SFDA website.
- The information posted will include company name, business address, or individual name, title, partially redacted Citizen National Identification Number, violation, administrative penalty decision, and duration of the prohibition. The posting will stay online for the duration of the prohibition or for two years if no specific duration is set out under the laws and regulations.
- After the expiration of the posting period, information on blacklisted companies or individuals will be moved to an archived database that is still publicly accessible.

WHAT ARE THE CONSEQUENCES AND IMPLICATIONS OF BEING BLACKLISTED?

Blacklisted companies or individuals can be prohibited from filing applications with SFDA, have permits revoked, and lose government contracts. For instance, the SFDA will check the blacklist and take the following actions:

- deny any application filed by a blacklisted applicant before the expiration of the prohibition period;
- conduct more frequent inspections and product quality testing on blacklisted companies; and
- send the blacklist to other government agencies, including the agencies responsible for development and reform, finance, tax, health, environment, science and technology, administration of industry and commerce, and others, to assist these agencies in making

decisions regarding procurement, review, approval, import and export, financing, providing credit, etc.

Of course, because the blacklist is publicly available on SFDA's website, blacklisted companies or individuals risk damage to their reputation and credibility among consumers and the healthcare community.

Note that the SFDA blacklist discussed herein is in addition to existing provincial blacklists required by the Ministry of Health ("MOH"). MOH notices from 2007 and 2010 require provincial departments of health to establish publicly available blacklists of companies engaging in commercial bribery during the purchase or sale of pharmaceutical products, and bar such companies from public tenders for two years. The new SFDA blacklist and pre-existing provincial department of health blacklists are parallel to, but somewhat different from, a recently centralized database of companies and individuals found guilty of certain bribery offenses. This database is searchable by the public but only by making a request to China's Supreme People's Procuratorate, as discussed in our previous e-alert.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our China life sciences practice:

Shaoyu Chen	86.10.5910.0509	chens@cov.com
Scott Cunningham	202.662.5275	scunningham@cov.com
Jason Ma	86.10.5910.0507	jma@cov.com
Eric Carlson	86.10.5910.0503	ecarlson@cov.com
Yan Luo	86.10.5910.0515	yluo@cov.com