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# White Collar Watch

The Newsletter of the White Collar and Government Enforcement Practice

## Increased cGMP Enforcement has Gone International: South Korean Action Against Johnson & Johnson Serves as Warning

By Christopher Hall and Matthew Smith

**IN BRIEF**

- **In both the United States and abroad, food and drug regulatory and enforcement agencies are increasing current Good Manufacturing Practices enforcement, including criminal sanctions.**
- **Companies manufacturing and selling products outside the United States should take heed of the increased international trend in enforcement actions.**

The U.S. Department of Justice has pursued criminal sanctions for current Good Manufacturing Practices ("cGMP")
violations with increasing frequency since roughly 2009. It now appears that our federal government is not alone. Other countries, with their own regulatory agencies mirroring the U.S. Food and Drug Administration, are stepping up their enforcement game. South Korea's recent enforcement action initiated against Johnson & Johnson regarding Children's Tylenol provides a good example.

Last month, South Korea's food and drug regulator, the Ministry of Food and Drug Safety ("MFDS"), announced its intention to open an investigation and seek criminal charges following a recent recall of 1.7 million bottles of Children's Tylenol produced by Johnson & Johnson's South Korea subsidiary Janssen Korea Ltd. The recall occurred earlier this spring after an audit discovered that some bottles of Children's Tylenol produced at the South Korean over-the-counter plant contained unusually high levels of acetaminophen, which can cause liver damage. Fortunately, no adverse reactions due to the error have been reported. The production error allegedly occurred when some bottles were manually filled, rather than using the automated process, because the filling machinery was broken.

The criminal investigation involves allegations that the company violated the country's Pharmaceutical Affairs Law and cGMP regulations. The government decided to file its criminal complaint against

Janssen Korea's CEO, Kim Oak-yeon, for manufacturing and selling dangerous medicine. If convicted, he faces up to three years in prison.

Prior to announcing the criminal investigation, South Korean officials had already ordered Johnson & Johnson to shut down manufacturing at the plant and suspend production of several products for varying periods of time ranging up to five months. According to Ministry spokesmen, production halts are a standard response to recalls in South Korea.

The MFDS has stated that its punitive measures are heavier than usual because of the company's multiple violations. With regard to the criminal investigation, the MFDS's focus seems to center on the fact that the company discovered the manufacturing anomalies in March and then sold approximately 38,000 bottles before notifying the agency. Pharmaceutical companies are obligated to immediately report any safety problems to the MFDS. The decision to bring charges may also stem, in part, from the risk involved to vulnerable customers — children.

South Korea's MFDS recently underwent a major organizational restructuring aimed at increasing its ability to protect consumers from unsafe products. Until just a few months ago, the agency was known as the Korea Food and Drug Administration. The South Korean administration's renaming and reorganization came just weeks after China's State Food and Drug Administration (now the China Food and Drug Administration ("CFDA")) underwent similar changes. Like China and its CFDA, South Korea restructured the MFDS as a ministry-level agency — primarily to address food safety concerns. The Korean agency's restructuring also involved decentralization. The MFDS now maintains one main office that oversees policymaking and development and numerous regional offices that handle enforcement, surveillance and monitoring. The changes will facilitate and promote monitoring, on-site inspections and enforcement.

These developments demonstrate a worldwide trend toward greater enforcement of cGMP standards. As pharmaceutical drug manufacturers develop emerging markets outside the United States, they would be wise to heed this trend and take a proactive approach to regulatory and cGMP compliance.



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