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US FDA issues warning letter to Taiwan Biotech

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The USFDA has sent a warning letter to Taiwan Biotech Company, one of the largest pharmaceutical companies in Taiwan.

On May 31, the U.S. FDA sent a letter of warning to Taiwan Biotech Company summarizing “significant violations of good manufacturing practice (GMP),”and asking them to take steps towards remedying the problems within the first half of June.

The FDA sent inspectors to the facility in Taoyuan in September 2017, and found that the firm failed to establish sound lab procedures for testing drug products and keeping detailed records, reported Taiwan News.

The primary areas of short-comings listed in the FDA letter are failures to; “establish an adequate system for monitoring environmental conditions in aseptic processing areas; and to follow an adequate written testing program designed to assess the stability characteristics of drug products.”

Further, Taiwan Biotech “failed to maintain written records so that data therein could be used for evaluating, at leastannually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures.”

The FDA has advised the company to consult with a GMP specialist to ensure compliance with U.S. standards.

The letter closes by stating that until Taiwan Biotech is in compliance with the GMP standards, the FDA may withhold approval of new product applications, and may eventually issue a complete refusal of products manufactured at the Taoyuan facility for sale in the United States.