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US FDA finds cGMP violation at Taiwan facility

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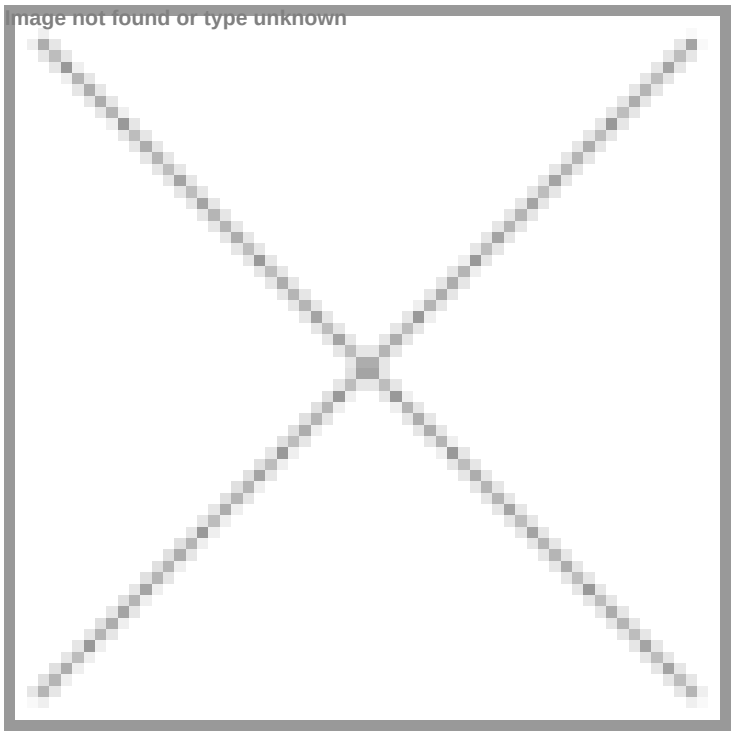

Singapore: The US Food and Drug Administration (FDA) has issued a warning letter to Taiwan Three Mast Pharmaceutical after an inspection of their pharmaceutical manufacturing facility in Tainan City.

The letter published on the US FDA website says the US FDA investigator identified significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals at the facility. "These violations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP. In addition, your Imbue Pain Relief Patch is an unapproved drug in violation of Sections 301(d) and 505(a) of the Act," states the letter.

The FDA has sought corrective steps in response to the letter. In addition to the cGMP violations, the letter says the firm also manufactures an over-the-counter (OTC) external analgesic drug product that violates sections 301(d), and 505(a) of the Act.