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ASIA EDITION

# Teva China API plant smacked by FDA warning letter, adding to drugmaker's burdens

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The FDA has nailed another Teva manufacturing facility with a warning letter, this time for an API facility in China. The Israel-based drugmaker in a short SEC filing said the letter had been issued April 10, following an inspection of the facility in September that found issues with the plant's manufacturing control and sampling processes.

Teva said it is already taking steps to deal with the FDA concerns "as well as the underlying causes of those concerns." It said it will provide the FDA a full response by May 1.

Later in the day, a Teva spokeswoman responded by email, repeating the language of the public filing but adding that, "As a matter of practice, Teva manufactures according to the highest quality and compliance standards." She said no supply interruptions are anticipated as a result of the warning letter. We do not anticipate any disruption in the supply of products to patients.

This is Teva's second warning letter in the last six months. In October, the FDA cited a Teva sterile injectables plant in Hungary, noting significant sterility concerns. The agency had earlier banned the plant from shipping any more products to the United States.

The newest citation adds to the burdens of the floundering company, which recently jettisoned its CEO and is reportedly looking at cutting as many as 6,000 jobs after Passover ends next week. It has been trying to significantly squeeze its costs following its $40.5 billion buyout of Allergan's generic drug business last year.