Lapses by EpiPen manufacturer tied to ‘serious’ problems, patient deaths, FDA says

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Jon Elswick/AP

A Pfizer unit that makes the EpiPen device for Mylan experienced a quality-control meltdown that included a failure to investigate “serious” problems associated with an unspecified number of patient deaths.

Throughout last year, Meridian Medical Technologies received hundreds of complaints that the EpiPen device, which is used to combat serious allergic reactions, failed to operate during life-threatening emergencies. Yet the Pfizer manufacturing unit not only failed to thoroughly investigate the problem, but did not initially remove potentially defective products.

The lapses were detailed in an extraordinarily disturbing Sept. 5 warning letter the Food and Drug Administration sent to the Pfizer unit and described the findings of an inspection last March.

“Your own data show that you received hundreds of complaints that your EpiPen products failed to operate during life-threatening emergencies, including some situations in which patients subsequently died,” the agency wrote to Meridian, adding that many of the complaints related to product activation failures.

Within days of the inspection, Mylan began recalling EpiPen devices from the U.S., as well as Europe, Asia, and North and South America, due to a product defect that, at the time, Mylan claimed “occurs rarely.”

The letter, however, portrays a more troubling picture.

For example, in April 2016, a customer complained that an EpiPen failed to activate, and Meridian confirmed the problem had first been seen two months earlier. But in June 2016, Meridian decided the defect was infrequent, even though the company had not determined the

extent of the problem or whether it was linked to the problem that was noticed previously, according to the warning letter.

Nonetheless, the Pfizer contract manufacturer shipped "multiple lots" of EpiPen devices that had been made using "the same potentially defective component," the FDA noted. Making matters worse, Meridian closed its investigation and determined 'no market action would be taken.'"

The FDA cited another concerning finding. Between 2014 and 2017, Meridian received 171 devices from patients who complained their devices failed to activate even when following instructions. But Meridian only examined some of the devices and told FDA inspectors they could not examine the rest without "approval by management," even while acknowledging this would be needed to confirm any defect.

A Mylan spokeswoman sent us a statement saying the company "will do whatever it can" to resolve the issues raised by the FDA. She added that the recall earlier this year was "a proactive and precautionary measure," and Mylan has "an unwavering commitment to quality and patient safety." Finally, the company does not anticipate any supply issues.

A Pfizer spokesman sent us note to say that, "between 2015 and now, we have shipped more than 30 million EpiPen Auto-Injectors globally. It's not unusual to receive product complaints, especially when the product is frequently administered by non-medically trained individuals. We currently have no information to indicate that there was any causal connection between these product complaints and any patient deaths." The company is working with the FDA, he added.

The manufacturing issues have been yet another setback for Mylan in its quest to maintain EpiPen as a big-selling product.

Last year, the device generated an estimated $1.1 billion in sales, but revenue has been declining due to increased competition. The expected fall-off follows controversy that erupted a year ago over steady price increases for the device, which costs between $650 and $735 for a two-pack for patients paying cash, according to GoodRx. Mylan responded by launching an authorized generic for $300.