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FDA: Epinephrine auto-injector device malfunctions can cause overdose

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The Food and Drug Administration (FDA) is advising anyone with Amneal Pharmaceuticals LLC or Impax Laboratories epinephrine injection, USP auto-injector 0.3 mg device to make sure it has a yellow stop collar that controls the dose of medicine administered. If the yellow stop collar is missing, there is a risk of overdose.

Anyone who received one of the devices after Dec. 20, 2018, is urged to inspect it. Affected lots from Amneal and Impax have NDC numbers 0115-1694-30 (case) and 0115-1694-49 (carton). Lot numbers and expiration dates are listed in a letter to health care providers on the FDA website.

To confirm that the yellow stop collar is present:

1. Remove the auto-injector from the carrying case.
2. Place the auto-injector on a flat surface.
3. Locate the edge of the label that states: “Peel here for further instructions.” Lift the label edge until you see the clear part of the auto-injector.
4. Look for the yellow stop collar inside the clear part of the auto-injector. If the yellow stop collar is not visible inside the clear part of the auto-injector, gently rotate the blue sheath remover, without pulling or removing the blue sheath remover, to see if the yellow stop collar comes into view inside the clear part of the auto-injector.
5. If yellow stop collar is present, then the product is safe to use. Re-wrap the label to its original position and place the auto-injector into the carrying case. No further action is necessary.

Call the Amneal Drug Safety Department at 1-877-835-5472 if the yellow stop collar is missing and return defective devices for a replacement. Patients should contact their pharmacy about a replacement epinephrine auto-injector before returning the defective device.

Report adverse events or quality problems to the FDA’s MedWatch program.