

Question 36 – April 16

What is true about biosimilars?

- A. In vivo studies on similarity to the reference product are needed for approval.
- B. They are copies of a biological agent, identical to the originator.
- C. They will likely be similar in cost to the originator.
- D. They are made with a different cell line and a different manufacturing and purification process than the originator.
- E. Interchangeability has been shown in robust clinical trials for the current biosimilars available in IBD.

Answer: D

Biosimilars are made with a different cell line than the originator, trying to attain the similar end product.

Reference

P T. 2013 May; 38(5): 270-274, 277, 287.