

Introduction to Biological Products, Including Vaccines, Biosimilars, Cell and Gene Therapies, and
Other Advanced Therapies

Quiz for CLE credit in the state of Ohio

Please complete and return to Coleen Carney at coleen.carney@fdli.org

Name: _____

Ohio State Bar Number: _____

1. In which year was the poison squad first created?

- a. 1910
- b. 1906
- c. 1904
- d. 1901

2. Under which act was REMS created?

- a. FDA Modernization Act of 1997
- b. Prescription Drug User Fee Act (PDUFA)
- c. FDA Amendments Act of 2007
- d. Biologics Price Competition and Innovation Act (BPCIA)

3. True or False: Warning and untitled letters are published.

- a. True
- b. False

4. List 4 actions you can take before litigation with a product specific proceeding.

- a. _____
- _____
- _____
- _____
- _____
- _____
- _____

5. True or False: Media can request information under FOIA.

- a. True
- b. False