

Introduction to Drug Law and Regulation
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. List two components to the definition of a drug:

- a. _____

2. True or False: A dietary supplement must be intended for ingestion.

- a. True
b. False

3. What is the purpose of a preclinical study?

- a. _____

4. True or False: the animal rule is available for drugs that can be approved under typical efficacy standards

- a. True
b. False

5. What does LPAD stand for and what is it's purpose?

- a. _____

6. Who is the current center director for CDER?

- a. Patrizia Cavazzoni
b. Jeff Shuren
c. Peter Marks
d. Susan Mayne

7. Which form outlines investigational findings?

- a. Form 526
b. Form 331
c. Form 483
d. Form 1571

8. List 2 major statutes and their significance.

- a. _____

9. List the three categories of DESI

- a. _____
- b. _____
- c. _____

10. What act succeed the Prescription Drug Marketing Act of 1987?

- a. Drug Price Competition and Patent Term Restoration Act
- b. Drug Quality and Security Act
- c. Durham-Humphries Act
- d. The CARES Act