FDLI 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

1. True or False: the statutory definition of "drug" excludes properly-labeled food and dietary supplements.
    a. True
    b. False
2. What is excluded in the definition of a tobacco product?
    a. Drugs
    b. Devices
    c. Combination products
    d. Tobacco marketed in combination with any other fda-regulated article
    e. Both a and d
    f. All of the above
3. How will FDA Regulate a "Shampoo"?
    a. As a Cosmetic
    b. As a Drug
    c. As a Medical Device
    d. Any of the above, depending on the manufacturer's "intended use" for the product
4. Which item is NOT an exception to the FDA's New Drug Definition?
    a. Grandfathered Drug
    b. Listed Drug
    c. DESI Drug
    d. GRASE
5. True or False: All New Drugs are Approved on the Basis of 2 Adequate and Well-Controlled Studies
    a. True
    b. False
    c. The speaker didn't cover this
6. Which Application does NOT need to include Patent-related Information?
    a. IND
    b. 505(b)(1) NDA
    c. 505(b)(2) NDA
    d. ANDA
7. What was Elixir Sulfanilamide originally marked for?
    a. Bronchitis
    b. Strep Infections
    c. Whooping Cough
    d. Pneumonia
8. What two new approval pathways did Hatch Waxman create?
    a. Answer:
        _____
        _____

9. True or False: Product sponsors are allowed to solicit informal feedback from FDA on scientific and regulatory matters via a phone call.
    a. True
    b. False
10. Who can initiate regulatory hearings?
    a. Answer:
    _____
    _____