Name: _____ Law Exam 1 2010

Form: 0

Version: 0

1. A prescription for Suboxone used for the treatment of drug addiction must include a special DEA number that starts with
   A. a 1 (one)
   B. a letter X
   C. a letter A, B, or F
   D. a zero
   E. a letter M

2. Which of the following laws significantly weakened the ability of the FDA to regulate dietary supplements?
   A. Prescription Drug Marketing Act of 1987
   B. Nutrition Labeling and Education Act of 1990
   C. Dietary and Supplement Health Education Act of 1994
   D. FDA Modernization Act of 1997
   E. Poison Prevention Act of 1970

3. Which of the following terms limits the amount of time a crime can be brought to trial?
   A. Administrative review
   B. Statute of limitations
   C. Breach limitations
   D. Contributory negligence
   E. Comparable negligence

4. Mrs. Nelson visits the pharmacy and requests to buy a particular OTC product, Drug A. Pharmacist Phil does not have Drug A in stock, but he does have Drug B in stock, which contains the same strength of drug, but is a prescription medicine. Since it is the same drug with the same strength, what could Phil do?
   A. Provide Drug B to Mrs. Nelson, charging her the price of Drug A.
   B. Provide Drug B to Mrs. Nelson after explaining to her that though the products have different names, they are the same thing.
   C. Provide Drug B to Mrs. Nelson after verifying with her that her condition requires the product.
   D. Explain to Mrs. Nelson that he is unable to provide her with Drug A at this time.

5. You receive a prescription for Nifedipine 60 mg Extended release tablets, which of the following products **can not** be used to fulfill this prescription legally?

073250 **AB**	No	NIFEDIPINE	CAPSULE; ORAL	10MG	NIFEDIPINE	CATALENT
072781 **AB**	No	NIFEDIPINE	CAPSULE; ORAL	10MG	NIFEDIPINE	INVERNESS MEDCL
018482 **AB**	Yes	NIFEDIPINE	CAPSULE; ORAL	10MG	PROCARDIA	PFIZER
077899 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	NIFEDIPINE	ACTAVIS
077899 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	NIFEDIPINE	ACTAVIS
020198 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	ADALAT CC	BAYER HLTHCARE
020198 **AB1**	Yes	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	ADALAT CC	BAYER HLTHCARE
020198 **AB1**	Yes	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	ADALAT CC	BAYER HLTHCARE
075269 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	NIFEDIPINE	BIOVAIL
075289 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	NIFEDIPINE	BIOVAIL
075269 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	NIFEDIPINE	BIOVAIL
075289 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	NIFEDIPINE	BIOVAIL
076070 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	NIFEDIPINE	BIOVAIL
075414 **BX**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	NIFEDIPINE	MARTEC USA LLC
077127 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	NIFEDIPINE	OSMOTICA PHARM
077127 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	NIFEDIPINE	OSMOTICA PHARM
077410 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	NIFEDIPINE	OSMOTICA PHARM

A. 073250
B. 077899
C. 020198
D. 077127
E. All of the options are acceptable to substitute for the requested product

6. A pharmacist in State A receives a prescription for Drug X. Under federal law, Drug X is allowed to have refills. However, a law in State A prohibits any refills for Drug X. If a prescriber were to authorize 3 refills on the prescription, should the pharmacist allow the patient to receive the refills?
   A. Yes, federal law controls over stricter state laws
   B. Yes, federal law preempts conflicting state laws
   C. No, pharmacists do not need to comply with conflicting federal laws
   D. No, stricter state laws not conflicting with federal laws must be followed

7. Evanscia is a product that is a roller pin like object that contains several small spikes and when rubbed across the skin reduces the incidence of acne. This is a
   A. food
   B. drug
   C. counterfiet drug
   D. device
   E. cosmetic

8. Which of the following sets of data would not be included in an NDA?
   A. Pre-Clinical
   B. Phase I
   C. Phase II
   D. Phase III
   E. Phase IV

9. Labeling as defined by the FDCA does not include
   A. Written material that accompanies a drug package.
   B. Printed material that accompanies a drug package.
   C. Graphic matter that accompanies ad drug package.
   D. An independent expert that discusses the product.
   E. A patient package insert.

10. The iPledge program requires which of the following?
    A. No more than a 90 day supply be supplied to the patient at one time
    B. Patient must use one form of birth control
    C. That only females register with the program
    D. That female patients have a pregnancy test prior to receiving a prescription for the medication
    E. That registration of the patient in the database only occur if the patient has a side effect

11. Which of the following must appear on a commercial container of a medication?
    A. Street address of the maker
    B. Date medication was packaged
    C. NDC
    D. Ingredient information
    E. All of the above

12. The 'Sulfanilamide Tragedy' led to the
    A. Pure Food and Drug Act
    B. Durham-Humphrey Amendment
    C. Federal Food, Drug, and Cosmetic Act
    D. Kefauver - Harris Amendment
    E. Food and Drug Administration Modernization Act

13. Which of the following was responsible for establishing two classes of drugs - prescription and over-the-counter?
    A. Durham-Humphrey Amendment
    B. Kefauver-Harris Amendment
    C. Prescription Drug Marketing Act
    D. Food and Drug Administration Modernization Act

14. Louisiana government differs from the federal government by which of the following?
    A. Louisiana does not have a chief executive
    B. Louisiana has four branches, where Federal has three branches
    C. Louisiana's Governor has line item veto power, where as the US President does not
    D. Louisiana's spending bills do not originate in a House of Representatives
    E. The Federal government has a judicial branch, where Louisiana does not

15. According to the excerpt from the orange book below, which of the following agents is the most appropriate to substitute for Adalat 90 mg Extended release tablets?

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020198 **AB1**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	30MG	ADALAT CC	BAYER HLT	
020198 **AB1**	Yes	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	ADALAT CC	BAYER HLT	
020198 **AB1**	Yes	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	ADALAT CC	BAYER HLT	
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077127 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	60MG	NIFEDIPINE	OSMOTICA	
077410 **AB2**	No	NIFEDIPINE	TABLET, EXTENDED RELEASE; ORAL	90MG	NIFEDIPINE	OSMOTICA	

A. 077410
B. 076070
C. 075414
D. 075289
E. None of these choices are bioequivalent to the requested product

16. During the Harco drugs v. Halloway case, Harco drugs documented all of their mistakes that they made at their pharmacies. Normally, this information is protected from being introduced into court cases. Why was the data allowed in this case to be presented to the jury?
    A. A single pharmacist made over 200 errors in one month.
    B. Pharmacies corrected the causes of their errors.
    C. Pharmacists filled out the forms incorrectly.
    D. Harco did not do quality improvement when they identified issues.
    E. No patients were ever harmed before.

17. Law's such as 'Emily's Law' as highlighted in the USA Today readings require
    A. pharmacists to have additional training in IV compounding.
    B. pharmacists to have additional training in any form of compounding.
    C. require technicians to recieve adequate training.
    D. require technicians to be certified.
    E. require technicians to be certified and pharmacists to recieve mandatory breaks.

18. A new health food company plans to sell cranberry tablets. The company would like to promote and advertise that the product increases the acidity of the urine and that it helps prevent against urinary tract infections. Which of the following would be the most accurate regarding these statements?
    A. Both statements about the product would likely not cause concern with the FDA.
    B. Only the statement promoting how the product increases urine acidity would likely be a concern for the FDA.
    C. Only the statement promoting how the product helps prevent against urinary tract infections would likely be a concern for the FDA.
    D. Both statements would likely be of concern for the FDA

19. What is the total number of members of the US Congress?
    A. 100
    B. 250
    C. 435
    D. 535
    E. 600

20. The connection between an error made in a pharmacy and the harm caused to a patient is considered to be
    A. damages.
    B. causation.
    C. duty of care.
    D. breach of duty.
    E. technical invalidation.

21. Which of the following is not required to be included on the label of a dispensed drug under the FDCA?
    A. The drug name
    B. The name and address of the dispenser
    C. The serial number of the prescription
    D. The name of the prescriber
    E. All of the above are required

22. Participants in the NDC system have an eleven digit code assigned to drug products, the first five digits of which identify the
    A. labeler.
    B. drug product.
    C. drug manufacturer.
    D. package size.
    E. drug name, size, and type.

23. Which of the following **best** describes a patient's right to be informed and to make a decision with that information?
    A. Consent
    B. Fidelity
    C. Respect for autonomy
    D. Confidentiality
    E. Justice

24. What is the abbreviation for solutions and powders for aerosolization that demonstrates that two different products are bioequivalent?
    A. AA
    B. AT
    C. AN
    D. AO
    E. AL

25. Which of the following is an accurate description of the type of defect that occurs when a drug causes significant side effects?
    A. Design defect
    B. Manufacturing defect
    C. Warning defect
    D. Education defect
    E. Technology defect

26. Which of the following is an example of adulteration?
    A. A product that is stored in a container that is light resistant.
    B. A product that is stored in an unsanitary container that is light resistant
    C. A product that claims to be another product
    D. An addictive substance that is placed in a container of any type

27. Which of the following is true regarding the medication patent?
    A. The innovator product maker has 19 years to market a product without a generic product being approved by the FDA.
    B. The first approved generic product has six weeks to market the generic drug without generic competition.
    C. The innovator product can add six months to the patent by completing pediatric studies.
    D. The innovator medication maker can 'purchase' additional patent life by paying the FDA a 10% commission of all sales per year up to 3 years.
    E. The generic medication can sell its product in the last year of the innovator medication's patent life.

28. A patient enters the pharmacy with a prescription that is written for the right drug, but that you do not feel is appropriate for this patient as it is extremely expensive. You (the pharmacist) contact the physician who is angry with you for suggesting another, cheaper product and advises you to not discuss it with the patient. You decide to discuss the issue with the patient to explain this other medication is cheaper and in your opinion just as effective. The patient agrees to discuss it with his physician and thanks you for your concern. This is an example of
    A. non-maleficence.
    B. beneficence.
    C. respecting the patient-physician relationship.
    D. confidentiality.
    E. privacy.

29. _____ is when one person is liable for the actions of another when engaged in some form of joint or collective activity.
    A. Vicarious liability
    B. The statute of limitations
    C. Causation
    D. Risk management
    E. Warning defect

30. Which of the following would exclude a chocolate candy from being considered a device?
    A. It undergoes a chemical reaction.
    B. It can be used to treat a disease.
    C. It can be used to cure a disease.
    D. It can help the function of the body.
    E. It is a machine.

31. Mrs. Smith and Mrs. Thompson are neighbors that both use Friendly Pharmacy for their prescription needs. Friendly Pharmacy misfilled one of Mrs. Thompson's prescriptions. Mrs. Thompson informed Mrs. Smith of the error. Mrs. Smith was outraged after learning about the error and now desires to sue Friendly Pharmacy. Would Mrs. Smith likely be successful in proceeding with a lawsuit?
    A. Yes. Mrs. Smith has a right to sue the pharmacy for any errors Friendly Pharmacy makes to help protect society.
    B. Yes. Mrs. Smith has a right to sue the pharmacy because Mrs. Thompson informed her of the error.
    C. No. Mrs. Smith had no harm caused to her by the error and has no interest to protect with a lawsuit.
    D. No. Mrs. Smith only learned of the error through her neighbor and not directly through the pharmacy.

32. Cheerios is a cereal that claims to promote a healthy heart by reducing cholesterol. Cheerios is a
    A. food.
    B. drug.
    C. counterfeit drug.
    D. device.
    E. cosmetic.

33. Which of the following is true about tamper-proof containers?
    A. The container must change colors if exposed to toxins.
    B. The evidence of tampering must be visually evident.
    C. The evidence of tampering must be evident to no less than 90% of adults.
    D. The seal must not be able to be broken by more than 20% of children.
    E. None of the above.

34. The Poison Prevention Act requires
    A. all medications be in child resistant containers.
    B. all oral medications be in child proof containers.
    C. most oral medications be in child proof containers.
    D. child resistant containers to allow no more than 20% of children to open them.
    E. child resistant containers to allow no less than 20% of adults to open them.

35. A chocolate covered candy is consumed for its flavor, however after eating large amounts of the material it reduces hunger. This would be considered to be a _____ __ per the FDCA
    A. device
    B. over the counter drug
    C. cosmetic
    D. food
    E. dietary supplement

36. Which of the following is true regarding the meaning of bioequivalence?
    A. Bioequivalence is when the rate of absorption is not the same as the brand name drug, however the drug still reaches the medication receptors at the same concentration.
    B. Bioequivalence is also known as a pharmaceutical alternative, but not a pharmaceutical equivalent.
    C. Bioequivalence and safety must be shown to be the same as a brand name drug before a generic can be approved by the FDA.
    D. Bioequivalence is when a generic drug shows the same rate of absorption and extent as a comparable brand name drug.
    E. Bioequivalence is required for an Advanced New Drug Application.

37. Which of the following means to give truthful information?
    A. Veracity
    B. Consent
    C. Respect for autonomy
    D. Nonmaleficence
    E. Beneficence

38. Which of the following statements is true?
    A. Veterinary medications are only available by prescription from a veterinary doctor
    B. Veterinary medications must be labeled so the patient can understand the risks and benefits
    C. Veterinary physicians may not prescribe human medications for animals
    D. Over the counter veterinary medications may contain 'Rx Only' human substances if labeled properly
    E. Veterinary medications may prescribed for use in humans

39. Which of the following were part of the Hatch/Waxman Act but did **not** benefit the brand name manufacturer of medications?
    A. Patent extension
    B. ANDA
    C. Market rights
    D. Right to defend patents
    E. Sample tracking rules

40. United States' House of Representatives serve for _____ years.
    A. 2
    B. 3
    C. 4
    D. 5
    E. 6

You have completed the test!