New Drug Approvals, 2014

Posttest

1. **Phase 2 of the clinical trials process:**
   - A. Includes 20 to 80 patients and the goal is to determine bioequivalence
   - B. Includes 100 to 300 patients and 1 of the goals is to establish the optimal dose of the drug***
   - C. Includes 1000 to 3000 patients and its focus is post-marketing surveillance
   - D. None of the above

**Correct Answer: B**
Answer is located in Table 2.

2. **Approximately how many investigational drugs make it past phase 2 studies?**
   - A. 10%
   - B. 20%
   - C. 30%***
   - D. 50%

**Correct Answer: C**
An estimated 70% of investigational drugs make it phase 1 studies; however, only about 30% of investigational agents make it past phase 2 studies.

3. **Medication guides (MedGuides):**
   - A. May be part of a REMS program
   - B. Are part of FDA-approved patient labeling for select products
   - C. Should be provided to the patient each time the drug is dispensed in the retail setting, provided the drug has a MedGuide as part of its labeling
   - D. All of the above***

**Correct Answer: D**
MedGuides can be included in REMS programs; although, most of the time they are only included if the REMS has ETASUs. MedGuides are considered FDA-approved patient labeling. According to FDA guidance, MedGuides should be provided to the patient each time a drug requiring a MeGuide is dispensed in the retail setting (Table 2).

4. **Afrezza, which was FDA-approved in 2014, is contraindicated in patients with which of the following conditions?**
   - A. Type 1 diabetes
   - B. Type 2 diabetes
   - C. COPD***
   - D. High cholesterol

**Correct Answer: C**
Afrezza is contraindicated in patients with chronic lung disease, such as those patients with COPD and asthma. It causes bronchospasm which can exacerbate both asthma and COPD symptoms.
5. **Olodaterol is indicated for which of the following conditions:**
   A. Diabetes
   B. Myocardial infarction
   C. COPD***
   D. Erectile dysfunction

**Correct Answer: C**
Olodaterol is a long-acting beta-2 agonist that is FDA-approved for patients with COPD.

6. **Naloxegol:**
   A. Is FDA-approved for the treatment of opioid-induced constipation
   B. Should be taken on an empty stomach
   C. Has an FDA-approved MedGuide
   D. All of the above***

**Correct Answer: D**
Naloxegol is FDA-approved for the treatment of opioid-induced constipation and is expected to be available in 2015; it should be taken on an empty stomach and should be dispensed with its MedGuide.

7. **With regard to the Orange Book’s therapeutic equivalence rating system, a product with an AB rating:**
   A. Requires further FDA evaluation
   B. Meets necessary bioequivalence standards***
   C. Has documented bioequivalence problems
   D. None of the above

**Correct Answer: B**
Answer is located in Table 4.

8. **Which of the following statements is correct?**
   A. OTC products that meet specific drug monograph requirements do not require FDA preapproval
   B. There is ongoing discussion centered on updating the OTC monograph system
   C. Manufacturers may request a switch from prescription-only to OTC status
   D. All of the above***

**Correct Answer: D**
Pharmaceutical companies who develop OTC products that meet FDA specific monograph requirements do not require FDA preapproval. Notably, the FDA is seeking to update its current system for approval of OTC drugs. The Agency held a public hearing in early 2014 to solicit ideas for potential updates to the existing OTC drug monograph process or proposals for a new regulatory system concerning these drug products. No final decision has been made as of this submission. The OTC monograph is not the only way an OTC drug gains marketing approval. A manufacturer may also submit an NDA or request to switch from a prescription-only to OTC status.
9. **Nexium 24HR is approved to treat heartburn that occurs:**
   - A. ≥ 1 day per week
   - B. ≥ 2 days per week**
   - C. Nexium is not approved to treat heartburn
   - D. None of the above

**Correct Answer: B**
Nexium 24HR is an OTC agent that is approved to treat heartburn that occurs ≥ 2 days per week.

10. **Patients who have which of the following conditions should consult their doctor before using nasal corticosteroids?**
   - A. Injuries to the nose
   - B. Tuberculosis
   - C. Glaucoma
   - D. All of the above***

**Correct Answer: D**
Patients with recent nose problems (such as injury, ulcers, surgery), infections (including tuberculosis, herpes eye infection), and certain eye problems (glaucoma, cataracts) should consult with their physician before using nasal corticosteroids.