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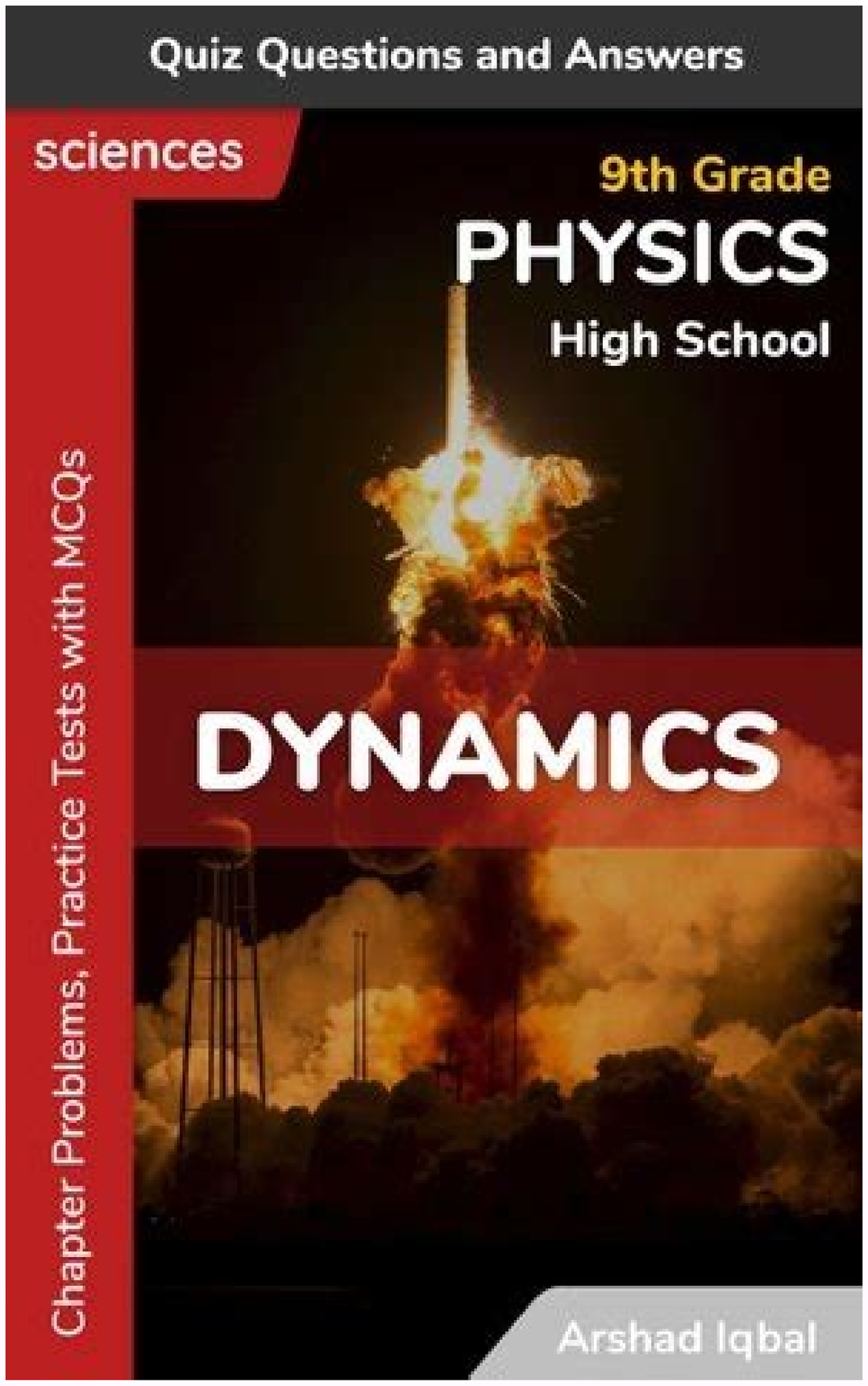
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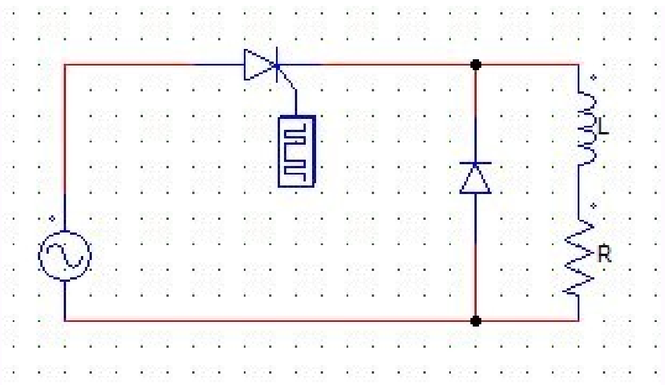

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Carbadox is an animal drug used in swine (hogs and pigs) for production purposes (e.g., increased rate of weight gain and improved feed efficiency) and therapeutic purposes (e.g., to control swine dysentery and bacterial swine enteritis). Carbadox is an animal drug shown to be carcinogenic in laboratory animals. While carbadox is also an antimicrobial, it does not pose the same resistance issues as other antimicrobials and is not considered important to human medicine. 2. What is the current status of the approved animal drug products containing carbadox? There are three approved New Animal Drug Applications (NADAs) for animal drug products containing carbadox, all held by Phibro Animal Health: Mecadox Premix 10 (NADA 041-061); contains carbadox alone Banminth/Mecadox (NADA 092-955); contains carbadox plus pyrantel tartrate Mecadox/Terramycin (NADA 141-211); contains carbadox plus oxytetracycline 3. How does the FDA regulate carcinogenic animal drugs? Under the Delaney Clause in section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA cannot approve a new animal drug application if it “is found to induce cancer when ingested by man or animal….” An exception to this general rule, referred to as the Diethylstilbestrol "DES" Proviso, allows for the approval of a carcinogenic drug if the FDA finds that, under the approved conditions of use, the drug will not adversely affect treated animals and no residues of the drug will be found by an approved regulatory method in any edible tissues of or foods from the animal. All animal drugs must also meet the standards of the General Safety Clause in 512 of the FD&C Act, which requires the agency to find that the drug is safe for both the animal it is intended for and humans who consume food products derived from that animal. 4. What are CVM’s concerns with respect to carbadox? CVM reviewed data available at the time it approved the 1998 supplemental applications for carbadox and made several conclusions about carbadox tissue residues based on that information. However, subsequent human food safety information demonstrates that carcinogenic carbadox residues persist longer than previously known. Because there is no established relationship between the noncarcinogenic residue quinoxaline-2-carboxylic acid (QCA) measured by the approved method and the residue of carcinogenic concern, the approved method measuring the concentration of QCA in animal tissue does not allow CVM to conclusively determine whether the residue of carcinogenic concern remains in the tissue. 5. Why did CVM propose to revoke the approved method for carbadox? On July 17, 2020, CVM displayed a proposed order that would, if finalized, revoke the approved regulatory method for carbadox because of FDA’s concern that it does not provide adequate information about carcinogenic residues of the drug. Interested persons had 60 days to comment on the proposed order. On the same day, CVM withdrew a previously published Notice of Opportunity for Hearing (NOOH) in the Federal Register that proposed to withdraw the approval of the drug applications for products containing carbadox. If the proposed order to revoke the currently approved method is finalized and the approved analytical method is revoked, CVM intends to publish in the Federal Register an NOOH proposing to withdraw approval of all new animal drug applications for use of carbadox based on the lack of an approved method to demonstrate that there is no residue of carcinogenic concern in the edible tissue of treated animals. 6. What is the expected impact of this action on the swine industry? If the order is finalized and the applications for carbadox ultimately withdrawn, carbadox will no longer be available for use by the swine industry. If this happens, the FDA will work to minimize impacts on the swine industry to the extent possible while ensuring the safety of the food supply. Other drugs are available for controlling swine dysentery and bacterial swine enteritis. Pork producers can also work with their veterinarian to implement preventative measures that reduce the need for a drug like carbadox, such as vaccination or changes in husbandry practices. 7. Should consumers stop eating pork products treated with carbadox? As a general matter, the FDA continues to advise all consumers to eat a well-balanced diet for good nutrition and to minimize potential adverse consequences from consuming an excess of any one food. The agency recognizes that pork is a common protein in American diets. Although the agency is not recommending that people make changes in their food choices during the time that CVM is working to remove the drug from the market, the agency offers this advice to consumers: Pork is a good source of protein; however, protein can also be found in other meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts and seeds. Select a variety of protein foods to improve nutrient intake and health benefits. 8. Does FDA have information about which pork products come from pigs that were treated with carbadox? No. Producers are not required to report to the FDA which drugs they use. 9. Why is FDA holding a Part 15 public hearing? CVM proposed to revoke the approved method for carbadox, which measures quinoxaline-2-carboxylic acid (QCA) as a marker residue to detect the presence of any residue of carcinogenic concern. (Determination of Carbadox (as Quinoxaline-2-Carboxylic [QCA]) Residues in Swine Liver and Muscle Tissues After Drug Withdrawal.) CVM’s proposed order was based on its determination that the method is inadequate to monitor the residue of carcinogenic concern in compliance with FDA's regulations in 21 CFR part 500, subpart E. These regulations set out the requirements for demonstrating that no residues of the drug will be found by an approved regulatory method in any edible tissues of or in any foods obtained from the animal, as required to meet the requirements of the DES Proviso. FDA regulations provide that the procedures in Part 15 apply when, among other things, the Commissioner concludes that it is in the public interest to permit people to present information and views at a public hearing on any matter pending before the Agency. On January 12, 2022, CVM announced it would hold a Part 15 public hearing at which the public could present scientific data and information related to the residue of carcinogenic concern for carbadox. Q: What causes endometriosis? A: The most widely accepted cause of the disease is retrograde menstruation. That means tissue from the uterine lining, called endometrial tissue, flows backward through a woman's fallopian tubes while she is menstruating. The tissue gets trapped and can't leave the body the way the rest of the endometrial lining does during menstruation. However, no matter where it is in the body, endometrial tissue still responds to hormonal stimulation each month. Endometriosis implants can become inflamed, bleed, and develop into scar tissue. When the implants are attached to organs in the pelvic and abdominal cavities severe pain, infertility and other problems may result. There are other theories about what causes endometriosis, including a deficient immune system response, hormonal imbalances or environmental causes. Experts also have found strong evidence to suggest a genetic link to the disease. Q: What does endometriosis feel like? A: Pain in the pelvic region is the most common symptom of the disease. Though some women who have endometriosis do not experience any symptoms. The degree of pain ranges from very mild to severe pain that can make it impossible for a woman to go about her normal life. Some women describe the pain as sharp and burning. It may last all month long, but is usually worse during menstruation, with deep penetration during sex, or with bowel movements. Some women report no pain at all. Other symptoms may include: abnormal menstrual bleedingsevere menstrual crampspelvic pain distinct from menstrual crampsbackachepain during or after sexual penetrationpainful bowel movementspain with exercisepainful pelvic examination Q: How can I be sure I'm being diagnosed correctly if pain associated with the disease can often be confused with other medical problems? A: If laparoscopy is not performed, sometimes your health care professional will prescribe hormonal treatments assuming endometriosis exists. If there is a response and decreased pain, there is an assumption that endometriosis was indeed the cause of the pain. However, endometriosis cannot be definitively diagnosed without laparoscopy and biopsy. The American College of Obstetricians and Gynecologists (ACOG) recommends a peritoneal (tissue) biopsy to confirm the presence of endometrial lesions. Q: Can I get pregnant if I have endometriosis? A: Yes, you can. Nearly all women who have endometriosis are fertile, and there are many women who have the disease and go on to have children. Endometriosis, unless it blocks the Fallopian tubes, is generally not thought to be an absolute barrier to contraception. Q: Is there any way I can prevent endometriosis? A: Unfortunately, the answer is probably not. Researchers cannot say with certainty what causes some women to get the disease while other women do not. Only 10 percent to 15 percent of all women in their reproductive years suffer from endometriosis. Q: What options are available to treat endometriosis? A: The most common medical therapies for endometriosis are hormonal contraceptives and other hormonal regimens, such as GnRH agonists (gonadotropin releasing hormone drugs), that control hormonal stimulation of the endometrial tissue. Danazol, a synthetic androgen, is also used, but it can cause some undesirable side effects, including weight gain, hirsutism (hair growth) and lowering of the voice. Surgical treatments range from removing only the endometrial implants by means of laparoscopy to removing the uterus and ovaries. Q: How do I know which is the best treatment option for my case of endometriosis? A: It's tough to know which is the best course of treatment for you, especially since no comparative studies have been conducted to determine which approach is better. There are pros and cons for all treatment options. Up to 90 percent of women with the disease will be helped by medical therapies. Oral contraceptives may be used indefinitely to manage symptoms. The goal of surgery is to remove the endometriosis, restore the normal anatomical relationship of the tissue, and remove any scar tissue caused by the condition. Most women choose laparoscopy if they decide to go with surgery. Many women try to avoid a hysterectomy if they can, since it's a radical procedure that will leave them infertile, with no guarantee that their endometriosis will be gone forever. Because of the risks associated with surgery, the usual course of treatment is to proceed from the least invasive or risky to the more invasive treatment. That means medical treatment is most often attempted first. If no success occurs after several trials of different types of medications, then laparoscopy may be recommended with hysterectomy as a last resort for most women depending on their age and their wish to preserve fertility.

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