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Food and Drug Administration Rockville MD 20857 Dennis Brydges Executive Officer Food and Agriculture Organization 1001 22nd Street, N.W. Washington, D.C. 20437 Dear Mr. Bridges: On behalf of the Food and Drug Administration, I am pleased to acknowledge your invitation to Mr. Sidney H. Rogers, Director, Investigation Branch to review the Food and Agricultural Organizations National Export Certification Program and its application in question for export practices. The trip will take place in Rome, Italy from July 10-27, 2002. In accordance with your letter of 12 May 2002, we understand that your organization will reimburse the cost of air fare, accommodation, meals and miscellaneous expenses. Once Mr. Rogers has returned and presented his claim, you will be notified by our Accounting Ledger branch of the amount to be refunded. Checks are to be paid to the Food and Drug Administration. Attached for your reference are some general details of fda guidelines who speak or attend outside seminars and conferences. Sincerely, Malcolm Frazier Director, Office of Resource Management EnclosureFMD 13 Distribution: Regional Food and Drug Directors and District Directors FDA Headquarters Office issued by: ORA/ORO/Division of Field Investigations (HFC-130) Publication Date: November 2002 By learning this simple imagery, students will be able to more easily identify the difference between lowercase b and lower case d to use them properly. Simply draw or imagine the word bed in lowercase letters as a real bed. A bed requires two end posts and a place to put a mattress. The post of b at the beginning of the word and entry of d at the end of the word serve as the bed posts and the body of the word creates an area on which one can place a mattress. Since the word bed contains both letters in question, it is easy to compare them and immediately see which one is which. See the simple picture included. Small children can benefit from imagining someone sleeping on the mattress. When one of my children is confused with b and d, I say, make your bed to remind the child of this imagery and he or she figures it out right away. These kinds of images allow children to learn and remember on their own rather than just giving them an answer that they can easily forget. In this section: What is hepatitis D? Hepatitis D is a viral infection that causes liver inflammation and damage. Inflammation is swelling that occurs when tissues in the body become damaged or infected. Inflammation can damage organs. Viruses invade normal cells in the body. Many viruses cause infections that can spread from person to person. The hepatitis D virus is rare because it can only infect you when you also have a hepatitis B virus infection. In this way, hepatitis D is a double infection. You can protect hepatitis D by protecting yourself against hepatitis B by receiving the hepatitis B vaccine. Hepatitis D spreads in the same way that hepatitis B spreads, through contact with an infected person's blood or other bodily fluids. The hepatitis D virus can cause an acute or chronic infection, or both. Acute hepatitis D Acute hepatitis D is a short-term infection. The symptoms of acute hepatitis D are the same as the symptoms of any type of hepatitis and are often more severe.<sup>19</sup> Sometimes your body can fight the infection and the virus disappears. Chronic hepatitis D Chronic hepatitis D is a long-term infection. Chronic hepatitis D occurs when your body cannot fight the virus and the virus does not disappear. People who have chronic hepatitis B and D develop complications more often and faster than people who have chronic hepatitis B alone.<sup>20</sup> How do hepatitis D and hepatitis B infections occur together? Hepatitis D and hepatitis B infections can occur together as a coinfection or a superinfection. People can only become infected with hepatitis D when they also have hepatitis B. Coinfection A coinfection occurs when you get both hepatitis D and hepatitis B infections at the same time. Coinfections usually cause acute, or short-term, hepatitis D and B infections. Coinfections can cause severe acute hepatitis. In most cases, people can recover from and fight the acute hepatitis D and B infections and viruses disappear. But in less than 5 percent of people with a coinfection, both infections become chronic and don't go away.<sup>21</sup> Superinfection A superinfection occurs if you already have chronic hepatitis B and then become infected with hepatitis D. When you get a superinfection, you may have severe acute hepatitis symptoms.<sup>19</sup> Up to 90 percent of people with a superinfection can't fight the hepatitis D virus, and develop chronic hepatitis D.<sup>20</sup> As a result, these people will have both chronic hepatitis D and chronic hepatitis B. How common is hepatitis D? Hepatitis D is not common in the United States. Hepatitis D is more common in other parts of the world, including Eastern and Southern Europe; Mediterranean and Middle East; parts of Asia, including Mongolia, Central Africa; and the Amazon River catchment area in South America.<sup>22,23</sup> Who is more likely to have hepatitis D? Hepatitis D infection occurs only in people who have hepatitis B. People are more likely to have hepatitis D in addition to hepatitis B if they What are the complications of acute hepatitis D? In rare cases, acute hepatitis D can lead to acute liver failure, a condition in which the liver suddenly fails. Although acute liver failure is uncommon, hepatitis D and B infections are more likely to lead to acute liver failure than hepatitis B infection alone.<sup>24</sup> What are the complications of chronic hepatitis D? Chronic hepatitis D can lead to cirrhosis, liver failure, and liver cancer. People who have chronic hepatitis B and D are more likely to develop these complications than people who have chronic hepatitis B alone.<sup>20</sup> Early diagnosis and treatment of chronic hepatitis B and D can lower your chances of developing serious health problems. Cirrhosis Cirrhosis is a condition in which the liver slowly breaks down and cannot work normally. Scar tissue replaces healthy liver tissue, partially blocking blood flow through the liver. In the early stages of cirrhosis, the liver continues to function. As cirrhosis gets worse, the liver begins to fail. Liver failure Also known as end-stage liver disease, liver failure progresses over months or years. With end-stage liver disease, the liver can no longer perform important functions or replace damaged cells. Liver cancer With chronic hepatitis B and chronic hepatitis D increases your chance of developing liver cancer. Your doctor may suggest blood tests and an ultrasound or other type of imaging test to check for liver cancer. Finding cancer at an early stage improves the risk of curing cancer. What are the symptoms of hepatitis D? Most people with acute hepatitis D have symptoms, which may include feeling tired nausea and vomiting bad appetite pain over the liver, in the upper abdomen darkening of the color of urine lighter by the color of feces yellowish hue to eyes and skin white, called jaundice In contrast, most people with chronic hepatitis D have few symptoms until complications develop, which could be several years after they were infected. Some symptoms of cirrhosis include weakness and feeling tired weight loss swelling in the abdominal swelling of the ankles, called edema itching skin jaundice What causes hepatitis D? Hepatitis D virus causes hepatitis D. The hepatitis D virus is spread through contact with an infected person's blood or other bodily fluids. Contact can occur by sharing drug needles or

other drug material with an infected person having unprotected sex with an infected person who receives an accidental sting with a needle that was used on an infected person The hepatitis D virus rarely spreads from mother to child during birth. You can't get hepatitis D from being coughed on or sneezing at by an infected person drinking water or eating food hugging an infected person shaking hands or holding hands with an infected person sharing spoons, forks, and other food utensils sitting next to an infected person How do doctors diagnose hepatitis D? Doctors diagnose hepatitis D based on your medical history, a physical examination, and blood tests. If you have hepatitis D, your doctor may do tests to check your liver. Medical History Your doctor will ask about your symptoms and about factors that may make you more likely to get hepatitis D. Physical examination During a physical examination, your doctor check for signs of liver damage such as changes in skin color swelling of the lower legs, feet, or ankle soreness or swelling of the abdomen What tests do doctors use to diagnose hepatitis D? Your doctor may order tests to check for liver damage, find out how much liver damage you have, or rule out other causes of liver disease. Blood tests Your doctor may order one or more blood tests to diagnose hepatitis D. A healthcare professional will take a blood sample from you and send the sample to a lab. Your doctor may order one or more blood tests to diagnose hepatitis D. Additional tests If you have chronic hepatitis D and hepatitis B, you could have liver damage. Your doctor may recommend tests to find out if you have liver damage or how much liver damage you have—or to rule out other causes of liver disease. These tests may include blood tests. elastography, a special ultrasound that measures the stiffness of your liver. a liver biopsy, where a doctor uses a needle to take a small piece of tissue from your liver. A pathologist will examine the tissue under a microscope to look for signs of injury or disease. Doctors usually use liver biopsy only if other tests do not provide enough information about liver damage or disease. Talk to your doctor about which tests are best for you. How do doctors treat hepatitis D? Doctors can treat chronic hepatitis D with drugs called interferons, such as peginterferon alpha-2a (Pegasys). In addition, researchers are studying new treatments for hepatitis D. These are usually medicines that are taken once daily by mouth. How do doctors treat the complications of hepatitis D? If chronic hepatitis D leads to cirrhosis, you should see a doctor specializing in liver diseases. Doctors can treat health problems related to cirrhosis with drugs, surgery, and other medical procedures. If you have cirrhosis, you have a greater chance of developing liver cancer. Your doctor may order an ultrasound or other type of imaging test to check liver cancer. If acute hepatitis D leads to acute liver failure, or if chronic hepatitis D leads to liver failure or liver cancer, you may need a liver transplant. How can I protect myself against hepatitis D infection? If you do not have hepatitis B, you can prevent hepatitis D infection by taking measures to prevent hepatitis B infection, such as getting the hepatitis B vaccine. If you do not get hepatitis B you cannot get hepatitis D. If you already have hepatitis B, you can take steps to prevent hepatitis D infection by not sharing drug needles or other medicinal materials wearing gloves if you have to touch another person's blood or open wounds not share personal things like toothbrushes, razors, or nail clippers How can I prevent spreading D to others? If you have D, follow the steps above to avoid spreading the infection. Your sexual partners should get a hepatitis B test and, if they are not infected, get hepatitis B vaccine. Preventing hepatitis B will also prevent hepatitis D. You can protect others from becoming infected by telling your doctor, dentist, and other health care professionals that you have hepatitis D. Don't donate blood or blood products, semen, organs, or tissue. Is a hepatitis D vaccine available? There is currently no hepatitis D vaccine. The Hepatitis B vaccine can prevent hepatitis D by preventing hepatitis B. Eating, diet, and nutrition for hepatitis D If you have hepatitis D, you should eat a balanced, healthy diet. Talk to your doctor about healthy eating. You should also avoid alcohol as it can cause more liver damage. References [19] Farci P, Niro GA. Clinical features of hepatitis D. Seminars in liver disease. 2012;32(3):228u2012236. [20] Ahn J, Gish RG. Hepatitis D virus: a call for screening. Gastroenterology & Hepatology. 2014;10(10):647u2012686. [21] Roy PK. Hepatitis D. Medscape website. . Updated March 16, 2017. Accessed June 5, 2017. [22] Rizzetto M. Hepatitis D virus: introduction and epidemiology. Cold Spring Harbor perspective in medicine. 2015;5(7):a021576. [23] Hoofnagle JH. Type D (Delta) hepatitis. Journal of the American Medical Association. 1989;261(9):1321–1325. [24] Negro F, Lok ASF. Pathogenesis, epidemiology, natural history and clinical manifestations of hepatitis D virus infection. UpToDate website. . Updated July 20, 2016. Accessed June 5, 2017. 2017.

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