EMORY UNIVERSITY SCHOOL OF LAW SPRING TERM, 1980

EXAMINATION

Food and Drug Law

Mr. Kitchens

This examination consists of four questions. Questions I and II are worth 35 points each. Questions III and IV are worth 15 points each. The exam is designed to be taken in two hours, but you have two and a half hours to complete it.

The only reference material you may use in taking the exam is the Federal Food, Drug and Cosmetic Act, as amended, together with any annotations or notes you have written in the margins of the printed Act.

Please sign the honor pledge below when you return your exam answers. Your copy of the exam questions is to be turned in with your answers. Because other students are taking the exam on May 6, you are not to discuss the exam with any other students until after that date.

If you wish me to notify you of your grade before grades are sent by the Law School, please call my secretary and leave your address or send me a self-addressed postcard or envelope.

HONOR PLEDGE:

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Exam Number

declaratory judgment that (1) DIUNIL is not a new drug and (2) FDA was without authority to classify DIUNIL as a new drug.

You are the law clerk to the District Court judge to whom Safechem's case has been assigned. The judge has requested you to analyze the issues presented in the litigation and to recommend an appropriate resolution. Set forth the substance of your memorandum.

QUESTION III (15 points)

All implanted and life-supporting or life-sustaining medical devices are required to have FDA approval for safety and effectiveness before they can be marketed unless the FDA determines that premarket approval is not necessary. Premarket approval can be required of other devices if general controls are not sufficient to assure safety and effectiveness and there is not enough information to establish a performance standard.

Likewise, a "new drug", as that term is defined in the Federal Food, Drug and Cosmetic Act (FDCA), may not be commercially marketed unless it has been approved as safe and effective by the FDA.

Compare the standards provided in the FDCA for determining the effectiveness of new drugs and devices. Are the standards similar? What distinctions, if any, exist?

The active ingredients in EVACNA and DIUNIL are identical, but the inactive ingredients are not the same. The inactive ingredients in DIUNIL, however, are individually considered by FDA to be generally recognized as safe.

The FDA has evidence which suggests that DIUNIL may be absorbed by the body more readily than EVACNA in which case the Safechem drug may cause elevated potassium levels that could lead to heart irregularities. The FDA has received no reports of injury associated with the use of DIUNIL.

The FDA has sent a regulatory letter to Safechem notifying the company that it considers DIUNIL a "new drug" and that since the drug is not the subject of an approved NDA, it cannot be marketed. The agency has requested data from Safechem relating to the manufacturing processes, quality control procedures and bioavailability and bioequivalence of DIUNIL and has sought assurances from the company that it will recall all DIUNIL now on the market and will submit an NDA for the drug. Safechem has refused these requests.

The FDA subsequently initiated a seizure action against DIUNIL in the United States District Court for the Northern District of Georgia. The agency simultaneously issued recall requests to distributors of DIUNIL and has issued press releases which state that the drug may pose a serious health hazard.

Safechem has filed a suit in federal court in Atlanta seeking a preliminary and permanent injunction (1) enjoining the pending seizure action and (2) enjoining the FDA from issuing further recall requests and press releases. Safechem also seeks a

QUESTION I (35 points)

You are general counsel to International Greenpak Company which manufactures a variety of canned food products, including Frespod® brand canned peas. The plant manager of Greenpak has recently informed you that quality control tests run at the plant have disclosed trace elements of polybugone, a toxic substance widely used as a pesticide chemical, in the canned peas produced at the plant from March 31 to April 18. There is also some evidence of lead migration from the solder used to seal the tin cans in which the peas are packaged. A majority of the peas produced during these production runs has already been shipped from the plant, but a small quantity is being held at the production facility for shipment in May.

At one o'clock Friday afternoon, April 25, you receive a telephone call from Greenpak's assistant plant manager. He states that an FDA inspector has arrived at the plant for an inspection and the plant manager and the quality control supervisor who usually escort government inspectors through the plant have left for the day. He further indicates that he is engaged in a clean up operation with a limited crew and had planned to close the plant at 2:30 p.m. although normally plant operations cease at five o'clock each day. He mentions that the FDA inspector has asked to see the company's records of interstate shipments of canned peas from the plant during the last six months and that the inspector has also expressed interest in examining production records, complaint files and test data maintained by the company.

He seeks your advice concerning whether he should allow the inspection and whether he should give the FDA inspector access to the requested materials.

1. What do you advise and why?
2. Suppose the FDA contends that Frespod® brand peas are adulterated and that Greenpak is in violation of Section 301(a) of the Federal Food, Drug and Cosmetic Act (FDCA):
   (a) What are the possible grounds for the adulteration charge?
   (b) What arguments, if any, could be made to defend against the adulteration charge?
3. What additional facts, if any, would be helpful for your analysis of parts 1 and 2?

QUESTION II (35 points)

Safechem Pharmaceutical Company manufactures a diuretic, or fluid-removing drug, under the brand name DIUNIL. Safechem has never filed an NDA for DIUNIL which is a generic version of EVACNA, a diuretic manufactured by Precision Laboratories. EVACNA was approved by FDA over 25 years ago and has been widely prescribed by physicians in the treatment of persons with heart and kidney diseases.