



EXAMINATION

Food and Drug Law

Mr. Kitchens

This examination consists of two questions. Question I is worth 50 points. Question II has two parts, Part A worth 35 points and Part B worth 15 points. 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 on your exam answers. Your copy of the exam questions is to be turned in with your answers; please write your exam number in the space provided below. Because other students are taking the exam at different times, you are not to discuss the exam with any other students until the end of the examination period.

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.

Exam Number

QUESTION I (50 points)

Consolidated Fullnet Corporation (Fullnet) is a large processor of seafood in this country. Fullnet's plant in Atlanta manufactures and sells in interstate commerce a variety of frozen seafood, including frozen breaded fish portions. Fullnet buys raw fish used in the manufacture of this product from the Wrightwet Seafood Company in Boston, Massachusetts. The breading used as an ingredient in Fullnet's product is purchased from the Crunchee-Dipt Breading Company in Nashville, Tennessee. Fullnet receives a written guarantee from Crunchee-Dipt stating that the breading is not adulterated or misbranded in violation of the federal Food, Drug and Cosmetic Act (FDCA).

On December 14 and 15, 1978, the Food and Drug Administration conducted a legal inspection of Fullnet's Atlanta plant. The following conditions and practices relating to the production of frozen breaded fish portions were observed:

- (1) Portions of the manufacturing equipment were not adequately cleaned prior to the beginning of the day's production. Accumulations of a brown powder-like material approximately 1/8-inch thick was present on product contact surfaces of several conveyor belts and associated machinery. Some product contact surfaces were rusty and paint was peeling from them.

- (2) Doors and windows leading to outside the building were opened and not screened. Flies were observed in some parts of the plant, including the production and packaging areas.

While at the plant, the FDA inspector collected several sub-samples of the brown powder-like material from product contact surfaces and several sub-samples of the breadings stored in the production facility. The inspector also collected ten samples of the finished packaged product, Fullnet's® frozen breaded fish portions, packed on Fullnet's production line on December 14 and 15, 1978.

FDA laboratory analyses revealed the presence of Peutrad mold, a type of machinery mold, in all sub-samples of the brown powder-like material and in eight of the ten samples of finished product. Peutrad mold is not considered a hazard to health and most of the mold fragments are killed during the final stages of processing. The FDA analyses also showed insect infestation in all sub-samples of the breadings but in only one sample of finished product.

The FDA laboratory analyses of the paper packages containing the finished fish portions showed concentrations of polychlorinated biphenyls (PCB's) in excess of 10 parts per million (ppm). PCB's are a group of toxic chemical compounds, which find their way into industrial waste and into various products, including recycled paper products. If such paper

claiming that Fullnet and company officers and employees, Stopshire, Fixx and Sweeper, had violated Section 301(a) of the FDCA by introducing into interstate commerce frozen breaded fish portions which were adulterated within the meaning of Section 402. A separate civil action was filed against Fullnet, repeating these allegations, and seeking to enjoin Fullnet from distributing lots of frozen breaded fish portions. The complaint also requested that Fullnet be ordered to recall such products now on the market so that the food could be destroyed or otherwise brought into compliance with the law.

- A. In what respects can FDA argue that the food is adulterated under Section 402? What arguments could be raised in defense by Fullnet?
- B. How should the Court rule on FDA's request for an injunction and recall? What factors should the Court consider in making this determination?
- C. What is the exposure of Messrs. Stopshire, Fixx and Sweeper to criminal liability? What defenses, if any, could each man raise to the charges?

QUESTION II

Part A (35 points)

Insta-Cure Laboratories, Inc. of Chicago, Illinois, is a manufacturer of prescription drugs and medical devices.

Section 520(e) of the federal Food, Drug and Cosmetic Act, added by the Medical Device Amendments of 1976, gave FDA authority to promulgate regulations relating to "restricted devices". Shortly after the 1976 Amendments became law, FDA published a notice in the Federal Register stating that "restricted devices" included all "prescription devices" as defined in 21 C.F.R. §801.109. The notice further disclosed that proposed regulations covering "restricted devices" would be published in future issues of the Federal Register, but no such regulations have been published at this time.

On April 10, 1979, FDA inspectors began a routine inspection of Insta-Cure's plant and asked to review production, control and complaint records for the medical devices manufactured by the company. Insta-Cure declined to allow the inspectors access to these records on the grounds that FDA lacked authority to inspect records, files, papers and other documents relating to "restricted devices" until such time as regulations had been properly promulgated by FDA under the 1976 Medical Device Amendments.

On April 17, 1979, Insta-Cure filed a complaint in the United States District Court for the Northern District of Illinois seeking a declaratory judgment that FDA lacked authority to inspect records at its plant relating to "restricted devices". FDA, in responding to the action, acknowledged that no regulation under Section 520(e) had been adopted in the manner required by Section 520(d) and that the notice published in the Federal Register shortly after the effective date of the Medical Device Amendments of 1976, did not comply with these rule-making requirements.

Insta-Cure recently began manufacturing a prescription drug under the brand name PERMADEX. No NDA or ANDA has been filed on PERMADEX; however, the drug, in its generic form, has been found to be safe and effective for the purposes for which Insta-Cure plans to market it.

1. On what basis can it be argued that PERMADEX is a "new drug" under the federal Food, Drug and Cosmetic Act?
2. What arguments could be made by Insta-Cure in support of the position that PERMADEX is not a "new drug"?
3. If PERMADEX is considered to be a "new drug", outline in general terms the procedure which must be followed by Insta-Cure before the drug can be marketed in this country.

Part B (15 points)

The medical devices manufactured by Insta-Cure are intended for use by or on the prescription of a physician or other licensed practitioner. These prescription devices are exempted from the statutory requirement that labeling for medical devices contain adequate directions for use. The exempting regulation for "prescription devices" was promulgated pursuant to FDA's general rule-making authority under Section 701(a) after adequate notice and opportunity for comment was given to interested parties. The regulation is codified at 21 C.F.R. §801.109 and defines a "prescription device" as a device which, because of potentiality for harmful use, the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a licensed practitioner.

products are used for packaging food, PCB's are likely to migrate into the food unless the food is protected from such migration by an impermeable barrier. Paper packaging material containing PCB's in excess of 10 ppm is not generally recognized as safe.

On January 17, 1979, the same FDA inspector returned to the Fullnet Atlanta plant and conducted another legal inspection. The same conditions and practices were observed as had been seen on December 14 and 15, 1978.

During both inspections, Fullnet's plant quality control manager, Noah Sweeper, accompanied the FDA inspector and was verbally warned about the insanitary conditions in the plant. Copies of the inspector's written reports of the December, 1978 and January, 1979 inspections, together with the FDA laboratory analyses, were provided Fullnet's plant manager, N. A. Fixx. In late January, 1979, FDA sent a letter fo Fullnet's president, Buck Stopshire, advising him of the insanitary conditions and requesting corrective action. At a meeting in February, 1979, Fullnet representatives advised FDA officials that steps were being taken to correct the plant conditions cited during the inspections. The FDA asked that all finished packages of Fullnet's® frozen breaded fish portions (approximately 400,000 packages worth about \$500,000) produced on the days of the inspections, be recalled and destroyed. Fullnet declined this request.

In April, 1979 FDA filed a criminal action in the United States District Court for the Northern District of Georgia

FDA, however, asserted that the notice was fair advice to the industry of FDA's position that the previously adopted "prescription device" regulation was sufficient to define "restricted devices" and that new regulations governing "restricted devices" would be necessary only for further restrictions on the sale, distribution or use of these devices.

You are the District Judge to which this case has been assigned, a judge not known for concise opinions that always respond to the arguments of the parties. Outline the substance of your opinion.