EMORY UNIVERSITY SCHOOL OF LAW
FALL TERM – 2001
FOOD AND DRUG LAW
(Law 680)

FINAL EXAMINATION **PROFESSOR KITCHENS**
DECEMBER 13, 2001 **EXAM NO. _____**

INSTRUCTIONS

1. The exam is designed to be completed in 2.0 hours, but you may take 2.5 hours to finish.

2. This exam is a "closed book" exam.

3. Please write your exam number on the exterior cover of your Bluebook and on the copy of the exam itself. When you have completed the exam, please place the exam inside the Bluebook. If you use more than one Bluebook, please indicate this fact on the cover of the Bluebook (e.g. "1 of 2").

4. The exam consists of three questions and 5 pages. Please check to determine that you have a complete copy of the exam and initial each page of the exam in the top right corner. Apportion your time appropriately among the three questions. Question I is worth 35 points. Question II is worth 35 points. Question III is worth 30 points and consists of subparts. You are to answer only **two** of the **five** subparts.

5. Other students in this course are taking the exam at another time. Therefore, you should not discuss the contents of the exam in the presence of others who have not taken it.

6. As has been previously discussed, you may use a computer to write your exam answers.

7. For those students who are not using computers, please write so that I will be able to read your answer. I cannot give credit for anything I cannot read.

8. I have attempted to avoid any ambiguity in the "facts" presented in Questions No. I and II; however, if you think you do not have sufficient facts to answer either question, state what facts are missing and explain how they would affect your conclusions.

9. The taking of this exam is governed by the Professional Conduct Code: "I acknowledge that in this, as in all other law school activities, I am bound by the Professional Conduct Code."

Initial

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QUESTION I – (35 POINTS)

The United States Food and Drug Administration ("FDA") is considering bringing a seizure action in the United District Court for the Northern District of Georgia against two products, NATURE'S OIL and NATURE'S TOPPING, manufactured by Mountain Lake Foods, Inc. ("Mountain Lake") in Atlanta.

NATURE'S OIL is undiluted black currant oil ("BCO"), a liquid obtained by squeezing black currant berry seeds. Mountain Lake markets NATURE'S OIL in capsules, which are to be swallowed whole. The capsules contain pure BCO – nothing more. The capsules are made from gelatin and glycerin and have no independent nutritive value. The gelatin and glycerin do not interact with or change the character of the BCO, but merely act as a container comparable to a bottle containing liquids marketed for oral ingestion. The label for NATURE'S OIL states that the product will "energize the body" and can be used "effectively as part of a weight loss plan."

Mountain Lake's other product, NATURE'S TOPPING, is made from whole wheat flour, sugar, ascorbic acid (Vitamin C), and dried algae from Lake Burton in the mountains of North Georgia. This product is sold as a dry topping to be used on cereal. All of the ingredients of NATURE'S TOPPING have been approved by FDA for use in food, except for the dried algae. However, the results from animal studies at a prestigious university show that the dried algae are safe and non-carcinogenic. The studies also found that the consumption of the dried algae lowered the cholesterol levels of the test animals. The label and promotional materials for the product make the following statement: "NATURE'S TOPPING is clinically proven to reduce LDL ("bad") cholesterol and total cholesterol by blocking cholesterol absorption. As a result, taken as directed, NATURE'S TOPPING will lower your cholesterol levels and help support your cardiovascular health."

During an inspection at Mountain Lake's production facility in September, 2001, the FDA investigator took samples of the food labels of these products, and video tapes prepared by Mountain Lake to promote NATURE'S TOPPING. The video tapes contained the same statements concerning cholesterol as appear on the food label, but in addition a person, identified as a user of the product, declares that "NATURE'S TOPPING will start to reduce your risk of heart disease within 30 days!" The FDA investigator was told by an employee of Mountain Lake that these video tapes had not been used for over nine months and that he had been instructed by the plant manager to destroy them several months ago.

You are an attorney in FDA's Office of the Chief Counsel and are asked to write a memorandum discussing the legal status of the products, NATURE'S OIL and NATURE'S TOPPING. Your memorandum should analyze the options that are available to FDA under the Federal Food Drug and Cosmetic Act ("FDCA") to regulate these two products. You should also comment on whether the filing of a seizure action would be justified, or whether there is a better strategy that, in your opinion, will provide the optimal course of action for the agency.

QUESTION II (35 POINTS)

Dr. Reg Stretcher is Chairman of the Urology Department at one of the premier cancer hospitals in this country. In the spring of 1998, Dr. Stretcher learned he had colon cancer. Being well aware that colon cancer is particularly resistant to both radiation and chemotherapy, he decided to be treated by adjuvant chemotherapy. In this treatment, toxic chemotherapy drugs are administered under the premise that they will increase in effectiveness when the tumor mass has been reduced and the remaining cancer is present in small, residual amounts.

For three months, chemotherapy drugs were injected directly into Reg Stretcher's abdomen. He then received another twelve months of intravenous drug treatment. Following the completion of this chemotherapy in July, 1999, his cancer was in total remission. In January, 2000, a routine follow-up CAT scan showed the cancer growing as a mass in a lymph node near Dr. Stretcher's liver. Dr. Stretcher was told that the

standard arsenal of medical intervention had been exhausted. There was, as the best medical wisdom had it, little to do but wait.

Dr. Stretcher, having joined the ranks of the "incurable," decided that his best chance for an effective treatment was to study his own cancer cells and attempt to develop therapies that were specific to his own cancer. Most drug therapies for cancer are developed through a one-size-fits all approach – candidate drugs are first screened in the test tube and in test animals against prototype tumors. Eventually, those drugs with promising results based on these preclinical studies are studied in human clinical investigations. Those cancer drugs that are approved by FDA tend to be standardized and seldom address the unique characteristics of a patient's particular tumor.

To initiate his goal of developing a made-to-measure medicine, Dr. Stretcher arranged to have a piece of his cancer excised from the base of his liver. From that specimen, cancerous cells were taken and placed in Petri dishes containing a plasma-like fluid with the nutrients and hormones necessary for cell growth. Analysis of the cancer cells harvested from the incubated cultures found a specific rearrangement of a gene called p53. The p53 gene normally restrains cell division in humans; however, when it's mutated, cells can grow willfully, which is to say they become cancerous.

Because of the difficulty of testing anti-cancer drugs in a Petri dish, it is necessary to have the cells grow as a tumor in an animal. Dr. Stretcher injected some of his cancer cells into the flanks of special, immune-deficient mice (i.e. mice in which foreign, human-cancer cells are allowed to grow). After significant research and consultation with imminent oncologists and medical researchers throughout the world, Dr. Stretcher decided to test an ancient Chinese herbal preparation, packaged and available over-the-counter under the name PC-V. Substantial data exist that PC-V restrains certain mutant genes in prostate-tumor cells.

Dr. Stretcher added PC-V to the regular diet of the immune-deficient mice carrying his colon cancer. Other tumor-bearing mice were fed the regular diet as a control. Within a few weeks, the tumors in the PC-V fed mice had shrunk by 80 percent, while the tumors in the control mice had continued to grow. After completing these studies, Dr. Stretcher immediately started taking large quantities of the PC-V herb. The only side effect he experienced was diarrhea, and he adjusted his dose until it was

tolerable. Twelve months later, he is still taking PC-V every day, and a recent CAT scan shows no sign of cancer.

1. Were the actions of Dr. Stretcher lawful?
2. If Dr. Stretcher wanted to initiate similar treatments for individuals with colon cancer as part of his private practice, are there any FDA regulatory requirements that he must follow?
3. Should Dr. Stretcher desire to form a company to commercialize PC-V and other herbs as cancer therapies, what, if any, involvement with FDA would be required?

QUESTION III (30 POINTS)

Answer **two** of the following five questions:

1. Does FDA have authority to allow *de minimus* levels of a carcinogenic food additive in food? Would your answer change if the added substance was classified as an environmental contaminant rather than a food additive?

2. Describe what is meant by a "defect action level" for food and the rationale for DALs.

3. Describe concisely the classification scheme for medical devices under the Federal Food, Drug, and Cosmetic Act.

4. After a medical device has been approved or cleared for commercial distribution by FDA, what types of problems or adverse events related to the use of the product must be reported to the FDA by the manufacturer?

5. Can the manufacturer of an approved "new drug" disseminate information concerning "off-label" uses of the drug? If so, are there any limits that govern the dissemination of this information?