EMORY UNIVERSITY SCHOOL OF LAW
FALL TERM – 2012
FOOD AND DRUG LAW
(EBB Class No. 680-04A-5121)

FINAL EXAMINATION
DECEMBER 11, 2012

PROFESSOR KITCHENS
EXAM NO. _____

INSTRUCTIONS

1. You have 3.0 hours to complete the exam.

2. This exam is an "open book" exam.

3. Please write your exam number and name of the course (or EBB number) on your exam answers. Also, please write your exam number on the copy of the exam itself. Your exam answers should be written in a new document (laptop users) or a Bluebook rather than on the copy of the exam questions. When you have completed the exam, please return the exam questions and all used scratch paper. 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 four questions and 5 pages (excluding this cover sheet). Please check to determine that you have a complete copy of the exam. Question I is worth 40 points, Question II 30 points, and Questions III and IV are each worth 15 points. Apportion your time appropriately. You may answer the four questions in any order you prefer.

5. Other students in this course may be 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. If you have installed Electronic Blue Book software, which is provided by the law school, you may use a computer to write your exam answers. 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.

7. 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." Your exam number affixed above signifies your acknowledgement of this pledge.

EMORY UNIVERSITY SCHOOL OF LAW
FALL TERM – 2012

FINAL EXAMINATION – FOOD AND DRUG LAW

QUESTION I (40 Points)

You are the General Counsel for a start-up company that is developing its first product. The President and Chief Executive Officer of the company returns from a meeting of the Board of Directors and sends you the following e-mail:

> "At our Board of Directors meeting today, we had a very useful and candid discussion about our progress and plans for the technology we are seeking to commercialize. That technology has been given the code name "Product Breakthrough" (PB). Our Research and Development Department believes PB has substantial market potential, and to date we have raised $100 million to bring this technology to market. It is clear to me that we have reached the stage in our development of PB where your advice concerning the regulatory and legal issues we may face will be critical to the future direction of our work.
>
> As you know, the success of PB will determine the strength and continued existence of the company. We cannot afford to make a regulatory mistake. We need to show investors in the company that we have a sophisticated strategy that is likely to get PB into the marketplace in a reasonable time frame. Without this, the Board of Directors and our Chief Financial Officer advise me that the current economic climate for start-ups is so competitive that we will have serious difficulty in obtaining the additional capital needed to see us through the continued development of the product and ultimately its commercial distribution.
>
> Our research and development situation can be summarized succinctly. PB is a unique, patented compound. The active ingredient of PB is extracted from *Sceletium tortuosam,* a succulent plant known by the San people of South Africa as "Kanna." Kanna has been shown to boost mental acuity and elevate mood. PB can be manufactured via chemical synthesis for use in 25 mg capsules. A more potent, injectable form of PB (containing 125 mg of Kanna) can also be manufactured by combining the natural plant source, Kanna, with human somatic (i.e., body) cells harvested from healthy individuals. By chance, we also discovered that a 20% form of PB (5 mg of Kanna), when mixed with pomegranate juice, makes a very tasty beverage and has some useful nutrition properties.
>
> We believe PB can be demonstrated to serve an important therapeutic function in persons with clinical depression. Kanna has been extensively tested by reputable toxicologists who have determined that Kanna is non-toxic, non-carcinogenic, and safe for human use. The capsule form of PB was also recently studied in a small randomized, double-blinded placebo controlled study at the

University of Western Ontario in Canada designed to show whether a 25 mg daily dose of PB enhances cognition in healthy, non-depressed subjects. A positive effect on mood was noted in the study, which was presented at the World Psychiatric Association International Congress in Prague earlier this month, but this study has not been published.

Moreover, we have given several physicians at two major teaching and research hospitals access to PB for evaluation. These physicians have administered both the capsule and the injectable dosage form of PB to 200 persons with clinical depression. Based on results seen in the 100 patients administered the injectable form, PB appears to result in more therapeutic benefit than was seen in the 100 patients who were administered the product in the capsule form. These physicians also tested the beverage form of PB under daily use by 100 healthy volunteers over a one month period. Although this form of PB had no measurable effect on depression, they found that it significantly lowered cholesterol levels in each person.

Obviously, there are a number of business and scientific issues confronting us. I need your judgment and counsel on how we should proceed based on current food and drug laws, regulations, and practice. Specifically, I need advice concerning the following:

A. How will "Product Breakthrough" be classified and regulated by the Food and Drug Administration?

B. Will any type of premarket approval be required for the use of PB to treat depression, and if so, could we face the potential for multiple regulatory approval schemes? Explain concisely the different FDA approval requirements that may be applicable for both the capsule or injectable form of PB when used to treat depression and describe any comparative regulatory difficulties associated with getting either of these formulations on the market in this country.

C. If you believe the expense associated with obtaining FDA approval of PB as a treatment for depression will significantly exceed our current capital ($100 million), could we develop PB in a way that will reduce the regulatory costs and allow us to get on the market in a year or two with a product with broad commercial appeal?

D. Does the testing that has been performed by physicians on PB at the two teaching and research institutions create any additional regulatory concerns and if so, what are they?

I know this covers a lot, but I urgently need a well-reasoned and organized memo that I can share with our senior management and Board of Directors. If you do not have enough information at this time to provide a definitive response on any particular issue, tell me what you need to know and how it will affect your recommendation. You should recognize that my tenure as President and CEO, and perhaps everyone's future here, depends on your delivering a clear strategy that is consistent with legal requirements and makes sense to the venture capitalists who fund our company."

As General Counsel to the company, what is your response?

QUESTION II (30 Points)

Taste Buds Inc. (TBI) manufactures a number of products sold in retail grocery stores. In September 2012, TBI began marketing a new cereal product that is comprised of GRAS substances and FDA approved food additives, including 150 mg of calcium carbonate per 30 gram serving, which is the FDA-determined reference amount customarily consumed per eating occasion for a cereal product. In addition to all required labeling information, the cereal label contains the statement "This cereal is a good source of calcium which helps strengthen bones." By regulation, FDA has established a Daily Reference Value (DRV) for calcium of 1,000 milligrams (mg) (i.e., the amount of calcium that should be consumed daily for adults and children of 4 or more years of age.)

FDA conducted a re-inspection of TBI's manufacturing plant in Atlanta on November 13-14, 2012. The FDA investigator presented proper credentials and a Notice of Inspection to the manager of the plant. The plant manager stated, "What, again? I thought you needed a warrant to come back within a year" and walked away disgustedly. An earlier inspection of TBI in December 2011 had resulted in the issuance of a FDA Form 483 that listed several deficiencies in good manufacturing practices (GMPs).

During this re-inspection, the FDA investigator observed the production line for the TBI cereal. While inspecting the raw materials area of the manufacturing plant, the investigator saw what appeared to be rodent urine and feces in proximity to bags holding whole grain wheat used in the manufacture of the cereal. The investigator also observed several dead insects adjacent to the storage bins where the finished cereal product was stored. The FDA investigator took photographs of these conditions over the objection of the plant manager. Analytical results from samples of the cereal product taken during the inspection by FDA showed no insect contamination or other filth in the product; however, the results showed the presence of a pesticide chemical residue.

The FDA investigator also took a sample of two mail-order pamphlets that had been prepared for the product. One pamphlet stated "adequate calcium intake throughout life, along with a healthy diet and regular exercise, builds and maintains good bone health and will reduce the risk of osteoporosis." The other pamphlet prominently features a pitcher of milk in proximity to a photograph of the TBI cereal box with the representation that "Taste

Buds Cereal, like milk, is a good source of dietary calcium." In examining other records at TBI, the FDA investigator discovered evidence which calls into question whether any of these pamphlets had actually been used in connection with the sale of the product.

You are an attorney in FDA's Office of Chief Counsel and are asked to write a memorandum discussing any potential violations of the Federal Food, Drug, and Cosmetic Act and FDA regulations that may be applicable to TBI and this cereal product. Your memorandum should note: (a) any further information or factual development that may be relevant to your final enforcement recommendation, and (b) any issues associated with the fact investigation performed by FDA to date.

QUESTION III (15 points)

AdvanceDay Biotech (ADB) is a corporation based in Atlanta, Georgia. ADP manufacturers and distributes a number of medical devices, including its newest products known as XO-1 Implant and XO-2 Putty. These devices are used to stimulate bone growth in long bones and the spine. Both devices were approved in mid-2010 by the Food and Drug Administration pursuant to a Humanitarian Device Exemption (HDE) for use as an alternative to the use of autologous bone (bone taken from the patient's own body, usually the pelvis) or an allograft (bone from other human donors) in compromised patients requiring lumbar spinal fusion. Examples of compromising factors that may limit the fusion of autologous or allograft bone in these patients include osteoporosis, smoking, and diabetes.

An FDA investigation of ADB has uncovered evidence that the president of ADB, Reg Stretcher, and its current sales manager, Ace Barker, instructed the sales representatives of ADB to promote the use of the XO-1 Implant and XO-2 Putty devices with a bone void filler, called Bonestrux, also manufactured by ADB, which had previously been cleared for marketing as a Class II device by FDA through the submission of a 510(k) by ADB.

In furtherance of that promotional activity, Mr. Barker was told by Mr. Stretcher to provide ADB's sales force with written "recipes" to be distributed to orthopedic surgeons, providing detailed instructions on how to mix the XO-1 and XO-2 products with Bonestrux. These recipes called for medical personnel to mold the combined devices into "rods" for use in lumbar spinal fusion surgery, a type of surgery that is done to eliminate motion at a painful vertebral segment.

The evidence shows that Mr. Stretcher knew that the molded rods, made from X0-1, X0-2, and Bonestrux, had never been studied in a clinical trial and had never been presented to or approved by the FDA for lumbar spinal fusion surgery. The reason the XO-1 and XO-2 products are mixed with Bonestrux is because without the application of the bone void filler as a mixing agent, the XO-1 and XO-2 products are at a competitive disadvantage with other legal products used in spinal surgery. FDA investigators also interviewed the surgeons who have used the molded rods and found that the surgeons

have been extremely pleased with the ultimate result in patients. Indeed, these physicians stated that these molded rods work better than any other product presently on the market, and they plan to continue using them for this type surgery.

You are an FDA attorney and are asked to write a succinct memorandum discussing the legal status of the molded rods. In particular, your memorandum should state what court action, or other enforcement action if any, the FDA should take. Regardless of whether you conclude that enforcement action is warranted against the company or any individuals, you should present the legal reasoning behind your recommendation.

QUESTION IV (15 points)

Answer **two** of the following **three** questions. Each question is worth 7.5 points.

A. What is the main purpose of the abbreviated new drug application process? What is required to get an ANDA approval?

B. When is a 510(k) submission required for medical devices? What determination must the FDA make when it evaluates a 510(k) submission?

C. You are the food and drug law counsel for a pharmaceutical manufacturer. The president of the company asks you to meet with her to discuss a Warning Letter she has received from the FDA. The letter informs her that the FDA has determined that the active ingredient in one of the company's principal drug products is unsafe. The letter states that the FDA wants the drug voluntarily taken off the market and would like the company to conduct a public education campaign to warn doctors and patients who have been using the drug that it is unsafe. Before entering into negotiations with the FDA, the company president wants to know if the FDA can force a removal of the drug from the market. She also asks you to describe briefly what action the company may face if it does not agree to the agency's demands. What is your response?