Exam Date & Time: 13-Sep-2021 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Regulatory Aspects of Food and Nutraceuticals [PQA-MRA204T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) What is the scope of nutraceutical market in India? (10)

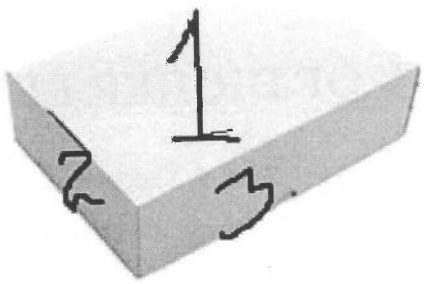
2) Is following advertisement issued by the company legal? Justify.

(10)

3) United Distributors Inc. has imported assorted chocolates manufactured by Chocolatier Guylian N.Y. weighing approximately 4000 kgs. These chocolates were essentially of 20 different types. Whereas, four types of the said chocolates were cleared, FSSAI had, by its letter dated 05.05.2014, refused to grant a no-objection certificate to the remaining 16 types of chocolates. According to FSSAI, eight types of chocolates were found to be non-compliant with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and the balance eight types of chocolates were found to be non-compliant with the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. Questions: 1.Explain the possible violation of Labelling Regulations and the solutions for the above consignment. 2.Explain the probable violation of food and additive regulations and solution for the above consignment. (10)

4) A dietary supplement containing multivitamins is packed in the container shown below. Write a representative label for surface 1, surface 2 and surface 3. (10)

about?



5) a) What types of work not performed by European Food Safety Authority in the food safety of EU? b) What for dietary reference values are used and explain the methodology for setting the same. (5+5 marks) (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Is the label shown below is of functional food or nutraceutical? Justify. (5)

Nutrition Facts

4 servings per container
Serving size 1 1/2 cup (208g)

Amount per serving
Calories **240**

	% Daily Value*
Total Fat 4g	5%
Saturated Fat 1.5g	8%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 430mg	19%
Total Carbohydrate 46g	17%
Dietary Fiber 7g	25%
Total Sugars 4g	
Includes 2g Added Sugars	4%
Protein 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

7) Motif food works is a Boston based donut manufacturing company started in the year 2004 and employs 322 FTEs (full time equivalent employees). From which date should they comply with DS cGMP rules? (5)

8) M/S AAK foods imports 1 million units of deep fried chips to India from Malaysia. After inspecting the consignment authorised officer informs the company that the label on the product is not as per the regulations. What are the options available to company as per Food Safety Standards (Import) order 2017? (5)

9) What are dietary supplements as per USFDA. (5)

10) What are the FIVE label statements required on the containers and packages as per USFDA? (5)

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