

Advisory Committee on Infused Product Manufacturing Facility Experience

Monday, April 29, 2019

1:00 PM – 5:00 PM

Truman Building, Fourth Floor

Room 493/494

Advisory Committee Members Present

Eric Hueste, DHSS – State of Missouri Executive Branch Member

Dr. Chris Riley – Public Member

Ray McCarty – Public Member

Department Staff Present

Lyndall Fraker, Section for Medical Marijuana Regulation, DHSS

Richard Moore, General Counsel, DHSS

Steve Doerhoff, Legal Counsel, DHSS

Lyndall Fraker, the Director of the Section for Medical Marijuana Regulation, Missouri Department of Health and Senior Services (“DHSS”) opened the meeting and introduced the committee members present.

Richard Moore, General Counsel, reported that the questions were previously sent to the committee members and feedback was given to the Department by the members. The public was also given the opportunity previously to submit comments on the questions. Richard Moore reported that once a question has been determined to meet the requirements of the committee, the committee members will be asked to establish what they believe to be the importance level of the question. Richard Moore reported that a scale was provided to committee members to make that determination. The scale is as follows:

- 1 – Slightly Important
- 2 – Important
- 3 – Highly Important
- 4 – Critically Important

Question 134:

Describe your experience, including the experience of any retained contractor or consultant, in food, beverage, nutraceutical manufacturing, including any relevant experience with medical marijuana.

Committee members recommended an amendment to the question.

Question as amended:

Describe your experience, including the experience of any retained contractor, consultant, or employee, in food, beverage, nutraceutical manufacturing, including any relevant experience with medical marijuana.

Weight of question: **4 – Critically Important**

Committee consensus to amend the question and on weight of question.

Question 135:

Will the facility consult with or hire a qualified chemist, pharmacist (with manufacturing or compounding experience), food scientist, or chemical engineer for consultation to establish their processes?

Weight of question: **3 – Highly Important**

Committee consensus on question and on weight of question.

Question 136:

Will the facility consult with or hire a qualified chemist, pharmacist (with manufacturing or compounding experience), food scientist, or chemical engineer for consultation after the processes are established?

Weight of question: **3 – Highly Important**

Committee consensus on question and on weight of question.

Question 137:

Describe your experience, including the experience of any retained contractor or consultant with extraction of chemicals from plant materials.

Committee members recommended an amendment to the question.

Question as amended:

Describe your experience, including the experience of any retained contractor, consultant, or employee, with extraction of chemicals from plant materials.

Weight of question: **4 – Critically Important**

Committee consensus to amend the question and on weight of question.

New Question 1:

Describe in detail the air-handling systems to ensure worker safety.

Weight of question: **3 – Highly Important**

Committee consensus on addition of question and on weight of question.

Question 138:

In addition to testing, describe the systems you have implemented, or plan to implement, to ensure the consistency of the ingredients in the product, to ensure that a) all the ingredients listed on the label are present, and b) any percentages of ingredients listed on the label are accurate.

Weight of question: **4 – Critically Important**

Committee consensus on question and weight of questions.

Richard Moore reported that the Department recommends deleting Question 139 because it is being worked into another question.

Question 139:

Describe your experience related to recalls.

Richard Moore reported that Question 139 is being deleted because it is being worked into another question.

Committee consensus on deletion of question.

Question 140:

Describe the system you plan to implement to ensure unacceptable products released into the market are recalled.

Weight of question: **3 – Highly Important**

Committee consensus on question and weight of question.

Question 141:

Describe your plans for waste storage and destruction.

Weight of question: **3 – Highly Important**

Committee consensus on question and weight of question.

Question 142:

Describe the system you plan to implement for handling flammable materials, explosive materials, and asphyxiates (such as carbon dioxide) to ensure worker safety and protection of the environment.

Weight of question: **4 – Critically Important**

Committee consensus on question and weight of question.

Question 143:

Describe your experience, including the experience of any retained contractor or consultant, and plans for quality control of products.

Committee members recommended amending the question.

Question as amended:

Describe your experience, including the experience of any retained contractor, consultant, or employee, and plans for quality control and quality assurance of products.

Weight of question: **4 – Critically Important**

Committee consensus on amending question and on weight of question.

Richard Moore reported that the Department recommends deleting Question 143.

Question 143:

Has the applicant ever been subject to a civil monetary penalty, criminal prosecution, seizure, or injunction by the FDA for practices in food or beverage manufacturing? If yes, please list.

Committee consensus on deletion of question.

The Advisory Committee voted unanimously in favor of accepting the questions as amended.
The meeting was concluded.