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QUESTION 1

One month prior to the anticipated approval date for your product, the marketing application that you submitted to a major regulatory authority has become the subject of an advisory committee meeting of experts convened by the regulatory authority. The advisory committee members unanimously vote not to approve your product because of a safety concern. Two days after the advisory committee meeting, the regulatory authority requests additional information to support the safety of your product. Assuming you have no additional data to provide, which of the following would be your MOST appropriate response to the regulatory authority\\'s request?

A. "Given the advisory committee\\'s unanimous decision, we know that the product will not be approved, and additional data will not make any difference."

B. "We have no additional informationto provide at this time, but wecan perform an additional analysis for a specific safety concern, if necessary."

C. "We disagree with the advisory committee\\'s decision because the committee neglected the thorough safety analysis that we provided."

D. "We have no additional information to provide at this time because we have already provided everything needed to support our product\\'s approval."

Correct Answer: B

QUESTION 2

A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?

A. Specification

B. Formulation

C. Property

D. Justification

Correct Answer: D

QUESTION 3

After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?

A. Resubmit the entire package.

B. Inform upper management immediately.

C. Contact the legal department and ask them how to proceed.

D. Verify the procedure in the regulation for the corrections.

Correct Answer: D

QUESTION 4

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

A. Product stability

B. Product registration

C. Product formulation

D. Product requirements

Correct Answer: A

QUESTION 5

Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?

A. "Product X is a guaranteed cure for arthritis."

B. "Product X is effective for the treatment of arthritis."

C. "Product X is safe for arthritis and without side effects."

D. "Product X is effective in all patients with arthritis."

Correct Answer: B