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QUESTION 1

During a routine review of promotional materials for a product, a regulatory affairs professional discovers an off-label indication. Which of the following would be the FIRST follow-up action for the regulatory affairs professional to take?

A. Allow doctors to use the product for the off-label indication.

B. Communicate with the sales department to stop using the promotional materials.

C. Contact the marketing department to recall the product.

D. Request that doctors stop using the product for the off-label indication.

Correct Answer: B

QUESTION 2

A superiority advertising claim for a product versus its competitor\\'s product can only be made under which of the following circumstances?

A. In vitro studies show the product to be superior.

B. Government survey data indicate the product is superior.

C. Results of a three-year, post-market patient survey indicate the product is superior.

D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Correct Answer: D

QUESTION 3

Which of the following claims would classify an apple as a drug?

A. "It will make you look younger."

B. "It will satisfy hunger."

C. "It will whiten teeth."

D. "It will prevent colds."

Correct Answer: D

QUESTION 4

The regulatory authority in Country X issued a request for a mandatory product recall in Country X due to serious

injuries to patients. This product also is distributed in Country Y.

What should the regulatory affairs professional of the product\\'s manufacturer FIRST do in Country Y?

A. Draft a formal letter to customers in Country Y about this recall.

B. Initiate a mandatory recall of the product in Country Y.

C. Review alt distribution records and complaints reported in Country Y.

D. Prepare the legal team in Country Y for possible litigations.

Correct Answer: C

QUESTION 5

A company is developing a new medical device. During which initial stage is it MOST appropriate (or a regulatory affairs professional to become involved?

A. Concept development and validation

B. Concept development and early technical design

C. Early technical design and product release

D. Product release and validation

Correct Answer: B