

Biogen Specific Teaching Material

FDA – Food and Drug Administration





Questions & Answers

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1. What is the FDA's principal mandate?

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1. The FDA's principal mandate is to protect the health of US citizens.

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2. Name as many categories of products and devices as you can which fall under the FDA's jurisdiction.

2. sample answers: Foods, drugs, biologics, medical devices, cosmetics, veterinary products & devices, tobacco-based prod., radiation-emitting devices

3. What product category does "dental devices" come under?

3. Dental devices falls under the category of medical devices.

4. What types of consequences could companies who deviate from the regulations face?

4. Company who deviate from the regulations may suffer closures, import bans, withdrawal of all products on the market.

5. Which devices do NOT fall under the category of medical devices?

5. PCs and laptops do not fall under the category of medical devices.

Thank you for your attention!

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