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FDA Questions for the Panel

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Question #1

Due to the long wear period for this device (90 days), the design of clinical studies is challenging. Please discuss the following

- The clinical study designs include long gaps between performance assessments (e.g., 30 days). Please discuss whether the type and amount of data available from the current clinical studies is adequate to represent sensor performance throughout the intended wear period. If not, please suggest the types of data that would be necessary for adequate system assessment.

- The current premarket clinical assessment does not include repeat sensor insertions. Please discuss any potential risks from repeated upper arm insertions (e.g., over many years) and whether current available data from premarket and ex-US studies (using previous sensor versions) are adequate to demonstrate safety of repeated insertions.

Question #2

Following clinical assessment, Senseonics has made four system design modifications. Please discuss whether there are important considerations related to safety or effectiveness that should be considered for each of the following four modifications. If so, please discuss the types of actions that may address those considerations.

- Modified glucose determination algorithm
- Modified transmitter design
- Modified sensor end-cap design
- Modified blunt dissector tool

Question #3

Senseonics has identified three drugs that may interfere with sensor readings: tetracycline, mannitol, and sorbitol. Please discuss whether Senseonics' proposed labeling mitigations are adequate for each drug interferent.

Question #4

If the device were to be found to be safe and effective based on existing data, Senseonics has proposed to conduct a post-approval study to gather additional information about their system. Please discuss the types of information, if any, that would be important to collect during such a study.

Ballot Questions for the Panel

- Is there reasonable assurance that the Senseonics Eversense Continuous Glucose Monitoring System is safe for the proposed indications for use?
- Is there reasonable assurance that the Senseonics Eversense Continuous Glucose Monitoring System is effective for the proposed indications for use?
- Do the benefits of the Senseonics Eversense Continuous Glucose Monitoring System outweigh the risks for the proposed indications for use?