24 Hour Summary
Anesthesiology and Respiratory Therapy Devices Panel
Advisory Committee Meeting
February 2, 2024

Introduction:

A meeting of the Anesthesiology and Respiratory Therapy Devices Panel ("the Panel") of the Medical Devices Advisory Committee was convened on February 2, 2024, to discuss and make recommendations related to pulse oximeter devices.

On February 2, 2024, the Panel discussed an approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters submitted for premarket review, taking into consideration a patient's skin pigmentation, and patient-reported race and ethnicity. This approach was presented in FDA's discussion paper published in November 2023 (https://www.fda.gov/media/173905/download). The Panel discussed the type and amount of data that should be provided by manufacturers to FDA to evaluate the performance of pulse oximeters submitted for premarket review, including prescription and over-the-counter indications, and labeling considerations.

FDA Questions/Panel Deliberations:

The Panel heard presentations from patients, clinicians, professional organizations, industry, and other stakeholders. The Panel agreed that the recommendations in the 2013 guidance document (https://www.fda.gov/media/72470/download) for pulse oximetry should be revised. The Panel discussed the advantages and challenges to the proposed clinical trial design outlined in the November 2023 discussion paper.

The Panel discussed tools for the assessment of skin pigmentation, including subjective scales, objective scales, and self-reported race/ethnicity. The panel was in agreement with the proposed use of the Monk Skin Tone Scale, and the inclusion of participants across the spectrum of Monk scores (at least 2 through 9) to promote diversity of skin pigmentation, race and ethnicity in these studies. The Panel was also in agreement with the use of Individual Typology Angle for objective measurement of skin pigmentation.

The Panel discussed the advantages and challenges to the proposed definition of non-disparate performance, and was in general agreement with FDA's proposed definition.

The Panel discussed over the counter pulse oximeters for medical purposes, including premarket clinical trial design, definition of non-disparate performance, and labeling.

In conclusion, the Panel agreed with FDA's proposed approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters taking into consideration a patient's skin pigmentation, race and ethnicity.

Open Public Hearing (OPH)

In the OPH session, the Panel heard presentations from clinicians and other stakeholders. Dr. Sam Ajizian spoke on behalf of Medtronic. Dr. Michael Abrams spoke on behalf of Public Citizen. Scott Lucas spoke on behalf of ECRI, a patient safety organization. Grace Wickerson spoke on behalf of the Federation of American Scientists, and Dr. Ashraf Fawzy spoke on behalf of the Johns Hopkins University research group.

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Transcripts:

Transcripts may be downloaded from:
February 2, 2024: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 02/02/2024 | FDA

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