National Alliance for Hispanic Health
1501 Sixteenth Street, N.W. • Washington, D.C. 20036-1401 • (202) 387-5000 • www.healthyamericas.org

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Contact: Adolph P. Falcón
(202) 797-4341
media@healthyamericas.org

Statement on FDA Issuing New Guidance on Enhancing Diversity of Clinical Trials

November 9, 2020. Washington, D.C. “Today the FDA strongly endorsed diversity in clinical trials as central to good science and drug safety.” said Dr. Jane L. Delgado, PhD, MS, President and CEO of the National Alliance for Hispanic Health, the nation’s leading Hispanic health advocacy group. ”Now responsibility for making it happen is with clinical trial sponsors and FDA review boards. The guidance must be a part of any future COVID-19 vaccine or drug approval.”

“The FDA recommendations for incorporation of community-based participatory research and fostering community engagement early in the design of clinical trials are essential. Both industry and the FDA must demonstrate through their future actions that diversity is central to any clinical trial design and approval. The status quo should no longer be acceptable to anyone,” concluded Dr. Delgado.

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Note please find relevant Clinical Trial Diversity Guidance links below.

- FDA Commissioner Statement: https://www.fda.gov/news-events/press-announcements/fda-offers-guidance-enhance-diversity-clinical-trials-encourage-inclusivity-medical-product

- Final FDA Guidance: https://www.fda.gov/media/127712/download