



November 27, 2019

Michael A. Carome, M.D.
Director
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Washington, DC 20009

Sidney M. Wolfe, M.D.
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Dear Dr. Carome and Dr. Wolfe:

Thank you for contacting the U.S. Food and Drug Administration (FDA) regarding a potential clinical investigation that tested sustained-release naltrexone implants in prison inmates. We appreciate hearing from you on this important issue.

We have referred this matter to FDA's Center for Drug Evaluation and Research for review and further action as appropriate.

Sincerely,

Martina Varnado
Director
Office of the Executive Secretariat, FDA