



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 26, 2020

Ernest C. Chisena, M.D. M.S.
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(b) (6)

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Sent via email to: echisenamd@gmail.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to force Exogen-Bioventus to prove that it is Ultrasound that is responsible for enhancing fracture healing, as claimed in their PMA was received by this office on 02/25/2020.

It was assigned docket number FDA-2020-P-0945. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)