

December 1, 2022

Daniel J. O'Leary Ombu Enterprises, LLC 3 Forest Ave. Swanzey, NH 03446

Sent via email to: OmbuEnterprises@msn.com

Dear Petitioner:

Your submission requesting that the FDA make the UDI information a publicly available field in the MAUDE database and the Recall database was received and processed under CFR 10.30 by this office on 11/30/2022.

It was assigned docket number FDA-2022-P-3053. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin Acting Director Dockets Management Staff FDA/Office of Operations (OO)