March 20, 2023

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

Sent via email to: OmbuEnterprises@msn.com

Re: Citizen Petition – Docket Number FDA-2022-P-3053

Dear Mr. O'Leary,

This letter responds to your citizen petition, received by the U.S. Food and Drug Administration (FDA, we, or the Agency) on November 30, 2022. In your petition, you request that FDA "take administrative action to make UDI information in the MAUDE database and the Recall database publicly available."

In accordance with 21 CFR 10.30(e) and for the reasons described below, your request is denied because FDA has determined that the action you request was taken by the Agency prior to the submission of your petition.

I. Decision Summary

On November 4, 2022, FDA's Center for Devices and Radiological Health (CDRH) announced via email[1] that it had "updated its public adverse event databases to include fields for the Unique Device Identifier – Device Identifier (UDI-DI) and a modified version of the complete Unique Device Identifier (UDI-Public) in the search results. The new fields are now available in the Manufacturer and User Facility Device Experience (MAUDE) database…"[2] If an adverse event result that is displayed in the public MAUDE database does not contain UDI information, it could mean that FDA did not receive UDI information in the associated report, or that the UDI information submitted as part of the associated report was not able to be verified by FDA.

In addition, UDI information is publicly available in the "Code Information" field of FDA's publicly-available Medical Device Recalls database,[3] and has been since the UDI rule was made

[1] A copy of this email, as well as information regarding joining FDA email distribution lists, can be found at https://content.govdelivery.com/accounts/USFDA/bulletins/332541a.
[2] The MAUDE database can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
[3] The Medical Device Recalls database can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

effective in 2013.[4] If the recall information displayed in the Medical Device Recalls database does not contain UDI information, it could mean that FDA did not receive UDI information as part of the submitted recall report.

II. Conclusion

For the reasons stated above, your petition is denied under 21 CFR 10.30(e).

If you have questions about this response, please contact Daniel Schieffer in our Office of Policy at Daniel.Schieffer@fda.hhs.gov.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.03.20 12:47:47 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
U.S. Food and Drug Administration

[4] Unique Device Identification System, 78 Fed. Reg. 58786 (September 24, 2013) at https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system.