OMBU
ENTERPRISES, LLC

3 Forest Ave.
Swanzey, NH 03446
Phone: 603-209-0600
E-mail: OmbuEnterprises@msn.com
www.OmbuEnterprises.com
EIN: 34-1997541

Petition on UDI in the MAUDE and Recall Databases

Date: November 30, 2022

The undersigned ("petitioner") submits this petition under 21 CFR §10.30 to request the Commissioner of Food and Drugs to take administrative action to make UDI information in the MAUDE database and the Recall database publicly available.

Action Requested
When a medical device manufacturer submits a Medical Device Report, MDR, under 21 CFR Part 803, one of the required fields is the Unique Device Identification, UDI. The Manufacturer and User Facility Device Experience database, MAUDE, does not make the UDI publicly available.

Similarly, a Correction and Removals report submission under 21 CFR Part 806 also requires UDI information. When FDA classifies the report as a recall, the Recall database does not make the UDI information publicly available.

This petition requests that FDA make the UDI information a publicly available field in the MAUDE database and the Recall database.

Statement of Grounds
One significant role of the publicly available elements in the subject databases is to provide specific information on adverse events and recalls related to medical devices. The reports provide information about the manufacturer and the device. However, the information may lack clarity and specifics because it does not include the UDI.

The final rule for the Unique Device Identification System, Docket No. FDA-2011-N-0090, includes the following statement in the Purpose section, “The identification system established under this rule will lead to more accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. It will allow FDA, health care providers, and industry to more rapidly extract useful information from adverse event reports, pinpoint the particular device at issue and thereby gain a better understanding of the underlying problems, and take appropriate, better-focused, corrective action.”

Because the publicly available fields in the databases do not include the UDI, the information, contrary to the purpose, is not available to allow health care providers or industry to extract the information and pinpoint the particular device at issue.

One application of the MAUDE database is analysis over time to support post-market surveillance, PMS, analysis. For example, trends in adverse reports for a Product Code can help identify issues and their changing patterns. Since the UDI-DI identifies the version or model of a device, the information would allow better determination of adverse event frequency and improvements at the specific device level.

Similarly, information from the Recall database, with UDI information available, can provide information that is more detailed and specific for device analysis.

Device information, including the UDI-DI, is publicly available from the AccessGUDID database. The descriptors often do not match the descriptors reported and published in MAUDE or the Recall database, so analysis cannot readily utilize the AccessGUDID information to infer the UDI from the databases.

The petitioner does not know of any information that may be unfavorable to the position in this petition.

Environmental Impact
This petition does not require an environmental impact statement because it falls under the categorical exclusion of 21 CFR §25.30(a) as a routine administrative or management activity. To the best of petitioner's knowledge, no extra ordinary circumstances exist.

Economic Impact
Pursuant to 21 CFR §10.30, petitioner will provide data concerning the economic impact of the action requested should such information be requested by the FDA.

Official Certification Statement
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Identifying Information

Daniel J. O'Leary
President Ombu Enterprises, LLC

Nov. 30, 2022
Date

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

OmbuEnterprises@msn.com
603-209-0600