MINUTES OF THE MEETING

Meeting Title:	**CDRRHR KAPIHAN**		
Date:	5 April 2024	**Time:**	8:00 AM - 3:00 PM
Minutes Taker:	Documentation Committee	**Location:**	FDA
Attendees:	CDRRHR Staff and Industry		

Coverage of the Regulation
Medical Devices which include in common terms
√ Medical equipment √ Hospital equipment √ Radiation Equipment and devices √ Medical supplies √ Prosthetics √ Condoms √ Disinfectant of MEDICAL DEVICES √ Dental Equipment √ In-vitro Diagnostic Products including Reagents and laboratory equipment NOTE: Medical devices are those used in medical applications. Those used in common laboratories, veterinary and manufacturing plants are NOT medical devices. Examples: a. Operating microscope being used as medical devices but used in the laboratory & research, it will not be a MD. **b.** Veterinary devices are not MD because they are not for human use.
Other Topics
Custom-made Medical Devices – CDRRHR will come-out with a clear regulation for this.
"Strictly for Exports" – CDRRHR will come-out with an announcement on MD for export only and not being sold and distributed in the Philippines are not required to be registered but need to apply under CMDL.
510K is not considered a product approval. The **Pre-market approval** is the MD registration in the US.
EU – Class A is self-declaration and **Classes B, C and D are full registration**.
China – full approval
IVD – The AO for IVD got delayed because it will have a provision on "For Export Only" and will require a CMDL. All those MDs "For Export Only" will be applied under CMDL.
Labels from CMDN to CMDR – the company will write a letter to CDRRHR to request for exhaustion. Over-labeling is allowed once the CMDR is released but needs FDA approval first prior distribution or importation. If registration number is machine printed, over-label is also allowed.
Retailer activity can be applied as additional activity to the distributor LTO.
List of Borderline Products will be released in the AMDD.
Labeling Guidelines will be released after the AO if IVD and the Amendment of AO 2018-002 are issued.

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"Groupings" is under CDRRHR review. Need to issue first the "Increase of Fees".
"Raw Materials" of the equipment – No need to submit the list of raw materials of the accessories.
Supermarkets, grocery stores, and other establishments selling medical devices will now be required to obtain a medical device retailer License to Operate (LTO).
Custom-Made MD definition will included in the revised AO. Custom-made devices are those specifically made for individual patients based on a prescription or order from a healthcare professional.
Upcoming Policies/Guidelines
Amendment of AO 2018-002 **AO for IVD** **Fees and Charges** **Amendment of AO 2020-017: Unified Licensing AO on Clinical Investigation**
Upcoming Event
Medical Device Congress (Nov 2024): Attendees will include regulatory agencies, medical device industry, medical device organizations, and consumers/end-users.
FDA Circular No. 2024-003 - Extension of the Regulatory Flexibility for Class B, C and D Medical Devices that are Not Included in the List of Registrable Medical Devices Based on FDA Circular No. 2020-001-A
• NON-registrable classes B, C & D products (FDA Circular No. 2021-001-A) can still apply for CMDN before Sept 30. • By September 30, applications considered to be "applied" are those that have been FILED AND PAID. • Proof of payment and doc track number are necessary proofs to consider the application as PENDING. • Those with expiring CMDN should apply for CMDR directly. • For Class B, C & D non-registrable products with CMDN, the MAH can apply for CMDR any time before the CMDN expires. • The MAH also needs to provide a letter (with attached CMDN copy) during application stating that the CMDN is applied for CMDR.

*Next Kapihan with CDRRHR will be on July 19, 2024.