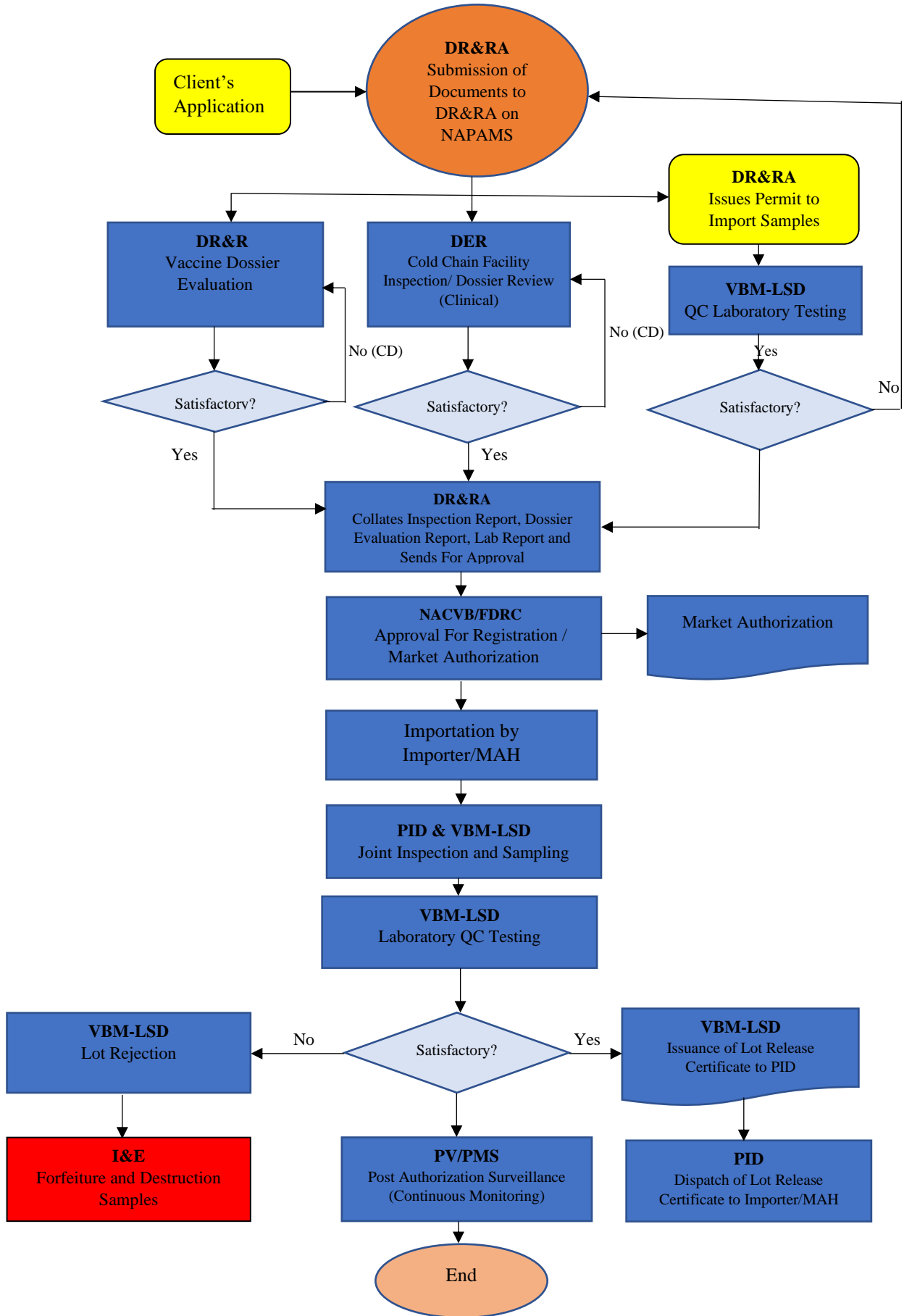


PROCESS MAPPING FOR VACCINES AND OTHER BIOLOGICALS IN NAFDAC



PROCESS MAPPING FOR VACCINES AND OTHER BIOLOGICALS IN NAFDAC

KEY

CD: Compliance Directive

DER: Drug Evaluation and Research Directorate

DR&R: Drug Registration and Regulatory Affairs Directorate

FDRC: Food and Drug registration Committee

NACVB: National Advisory Committee on Vaccine and Biologicals

NAPAMS: NAFDAC Product Administration and Management System.

PID: Ports inspection Directorate

PV/PMS: Pharmacovigilance and Post Market Surveillance

QC: Quality Control

VBM-LSD: Vaccine, biologicals, and Medical Devices Lab Services Directorate

NAFDAC- National Agency for Food and Drug Administration and Control

MAH- Marketing Authorization Holder

TIMELINES FOR DIRECTORATE PROCESSES

DER: Cold Chain Facility Inspection/ Dossier Review (Clinical)-40 Working days

VBM-LSD: QC Testing and issuance of Lot release Certificate-40 Working days

DR&R: Registration& Vaccine Dossier Evaluation-35 working days

PID: Dispatch of Lot Release Certificate-3working days

PMS : Post Market Surveillance- Continuous