FDA
Food and Drug Administration
PHILIPPINES

Public Symposium on Rethinking Regulations in the Era of the Fourth Industrial Revolution

FOOD AND DRUG ADMINISTRATION

18 January 2019

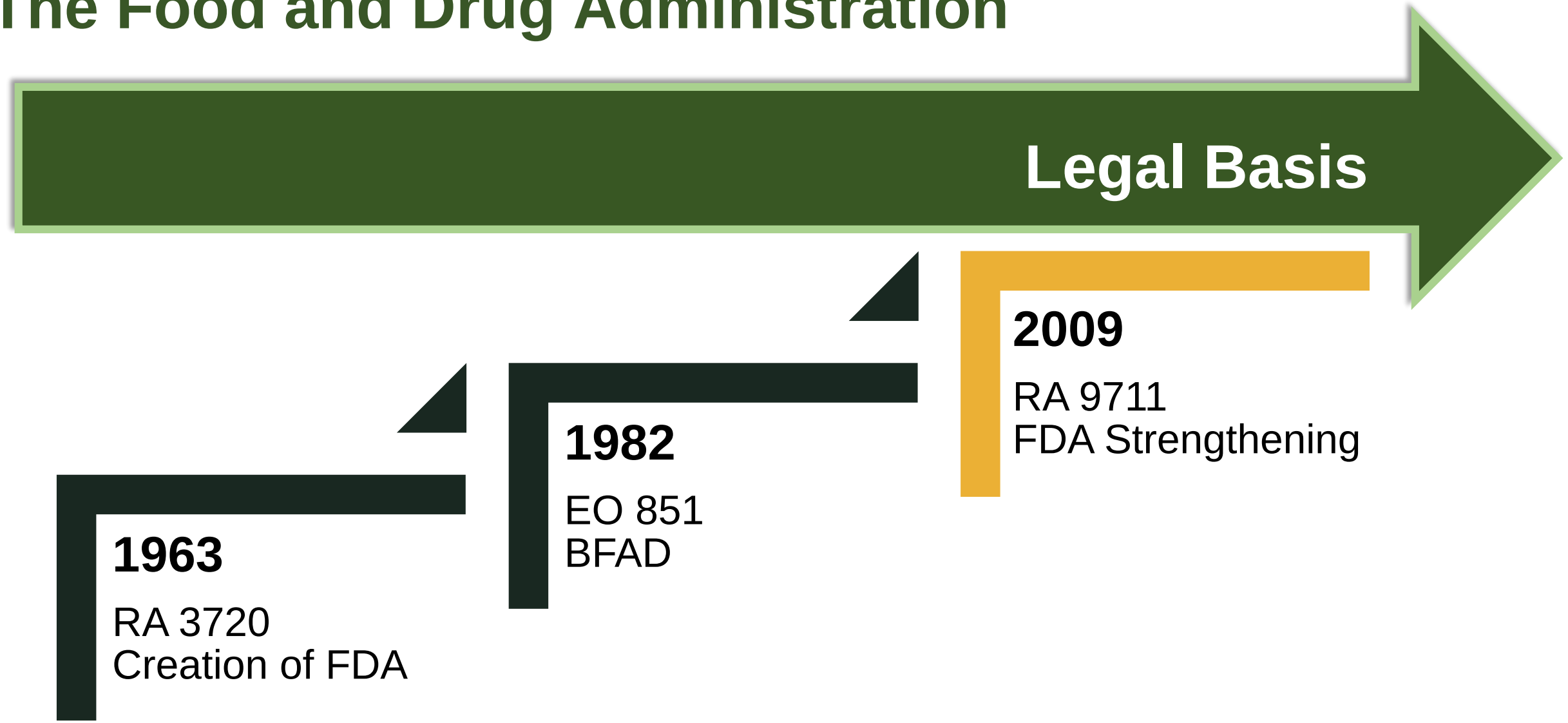
AGENDA

1. About FDA

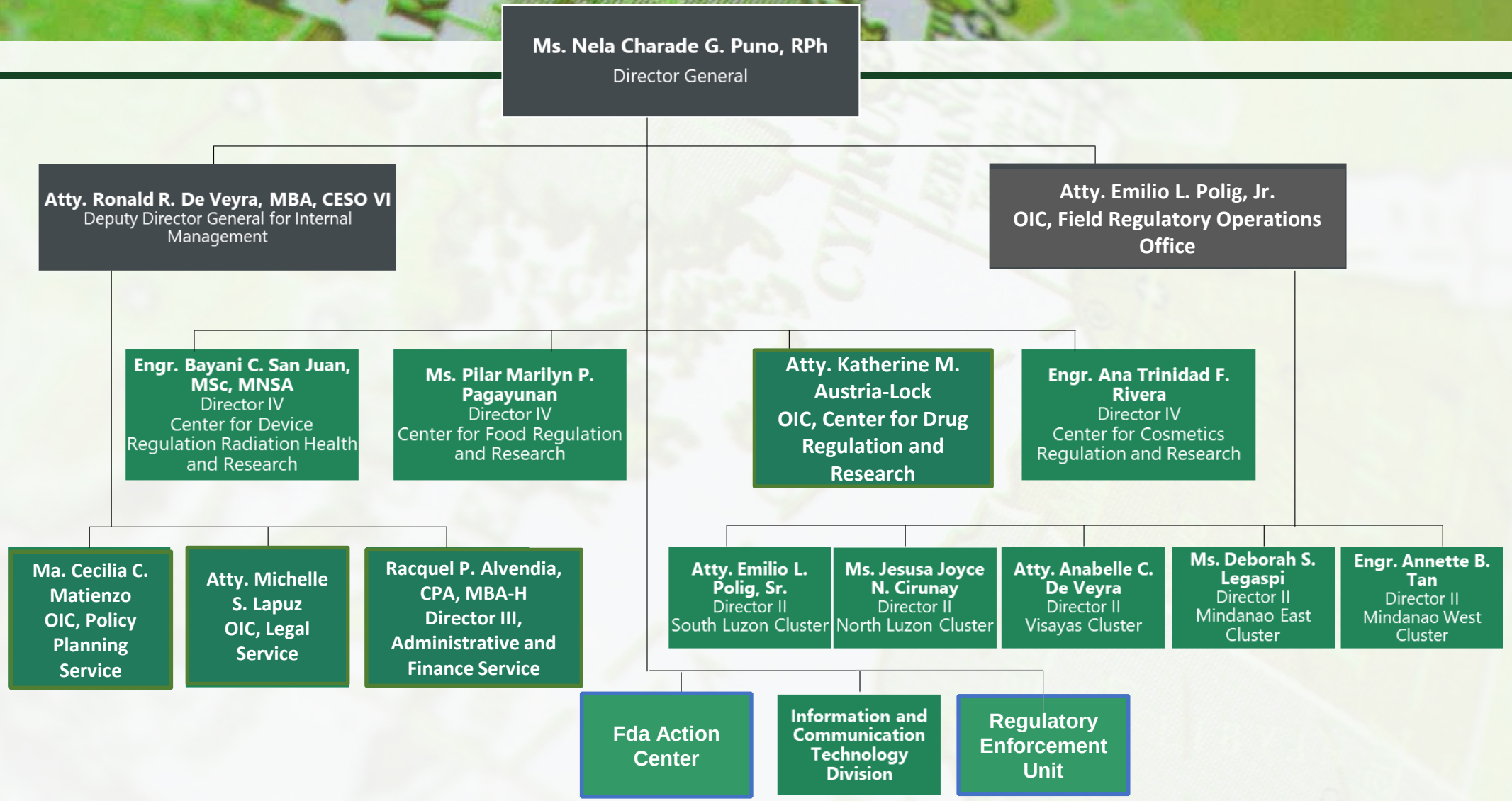
2. Regulatory Framework

3. Way Forward

The Food and Drug Administration



Current Organogam



The Four Centers of the FDA

Health Product Center	Product Jurisdiction				
 Center for Cosmetics Regulation and Research	Cosmetic Products	Household/ Urban Hazardous Substances	Household Pesticides	Toys and Childcare Articles	
 Center for Drug Regulation and Research	Human Drug Products	Veterinary Drug Products	Medical Oxygen	Traditional Medicine	Vaccine and Biological Products
 Center for Food Regulation and Research	Processed Food Products	Raw Materials for Food	Food Supplements		
 Center for Device Regulation, Radiation Health and Research	Medical Devices	Radiation-emitting Devices	Health-related Devices	Radiation Facilities	

REGULATORY FRAMEWORK

Licensing and Inspection

Pre-Market Approval

Post-marketing Surveillance

FDA Core Funtions

Licensing of Establishments

- *Manufacturers*
- *Traders*
- *Distributors/ Importers/ Exporters/ Wholesalers*
- *Retailers/ (Drugstores)/ Operators/ Applicators*

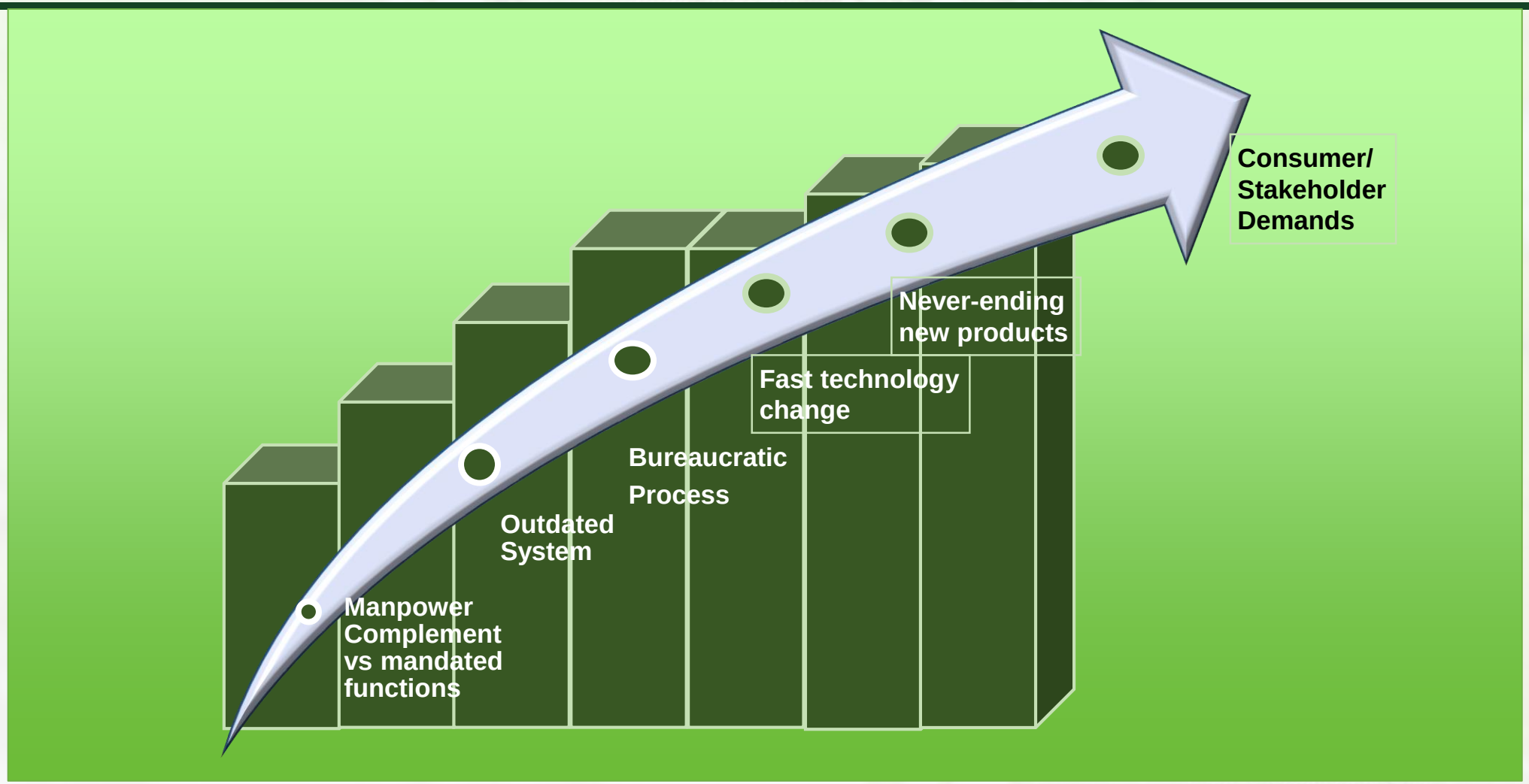
Registration of Health Products

- *Drug*
- *Food and Food Supplements*
- *Medical Devices*
- *Household/Urban Pesticides*
- *Cosmetics (Notification)*
- *Toys and Childcare Articles (Notification)*

Post-Marketing Surveillance

- *Inspection*
- *Health Product Vigilance*
- *Enforcement*
- *Advertisements and Promotions Regulation*

Barriers and Challenges



WAY FORWARD

FDA Three Marching Orders

72-hour Turnaround Time

Zero Backlog

Strengthened Enforcement

FDA ACTION CENTER (FDAC)

Bringing the services nearer to our stakeholders

Ease of Doing Business

EASE OF DOING BUSINESS

R.A. 11032

PROJECT REPEAL

The Philippine Red Tape Challenge

DONE

FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER

Regulatory Impact Assessment

KKK PROGRAM

KAAGAPAY SA KALUSUGAN AT KALIGTASAN

Main Objective: Improve turnaround time for laboratory testing of government procured pharmaceutical products

MSME: DTI-DOH-FDA Program

FOCUS: Micro Enterprise of Food Products: Pilot Program

License to Operate

OLD PROCESS

- APPLICANT START
- PAYMENT
- INSPECTION
- EVALUATION / CHECKING
- APPROVAL / DENIAL
- ISSUANCE OF LTO/LOD
- PRINTING & RELEASING

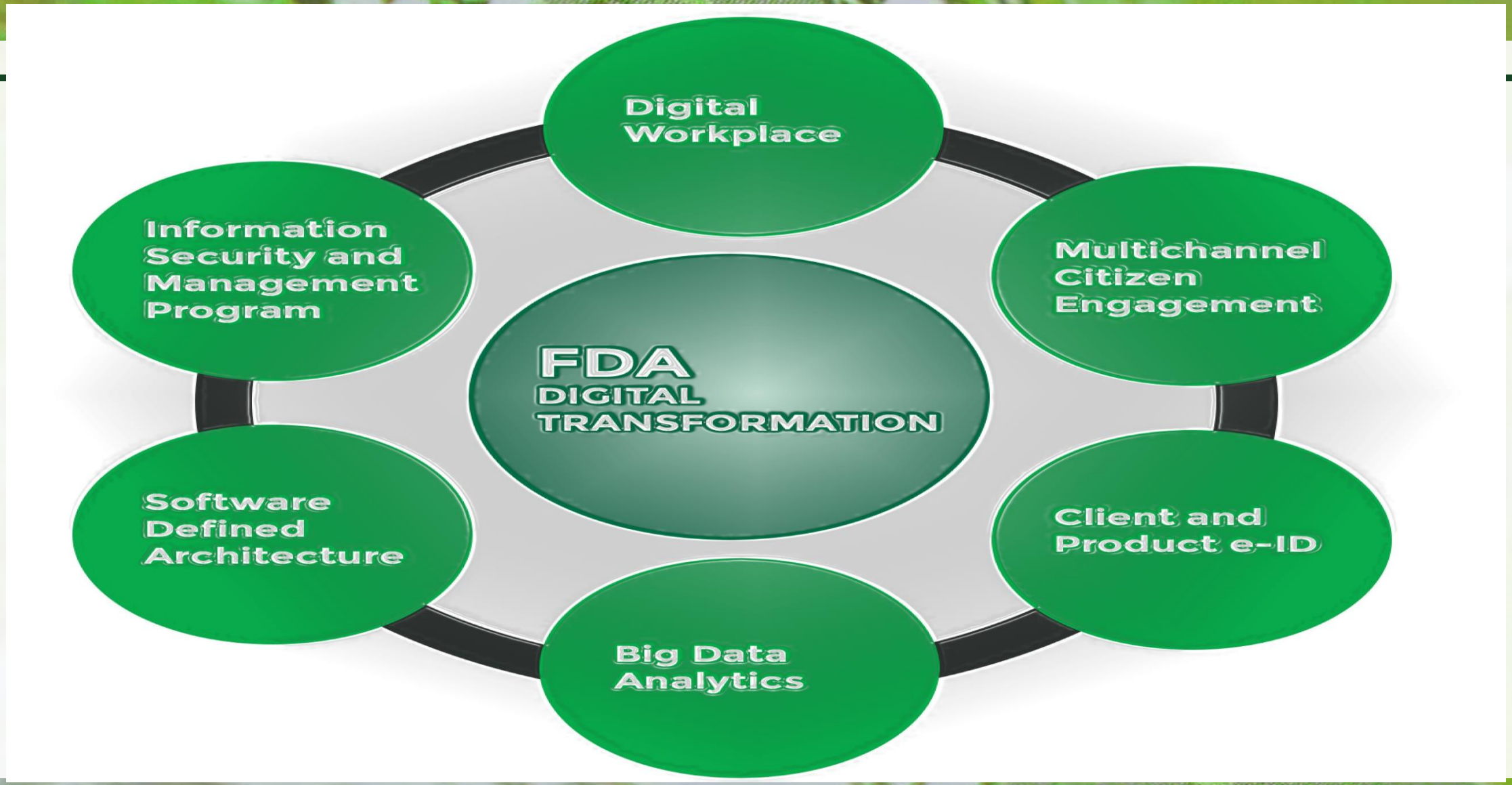
90 CALENDAR DAYS PROCESSING TIME

PROGRAM

- PRE-ASSESSMENT AND ISSUANCE OF LETTER OF ENDORSEMENT
- APPLICATION START
- CONDUCT OF INSPECTION
- EVALUATION OF APPLICATION
- PRINTING & RELEASING

15 CALENDAR DAYS PROCESSING TIME

DIGITAL TRANSFORMATION



International Alignment

- **Harmonization of Technical Requirement and Standards**
- **FDA Accession Plan**

  - ❑ Pharmaceutical Inspectorate Cooperation Scheme PIC/S (>45 countries)
  - ❑ WHO Global Benchmarking Tool (pre-qualification for WHO listed inspectorate)
  - ❑ ASEAN GMP Mutual Recognition Arrangement (MRA)

#FDA
20/20
VISION

Thank you!