U.S. FOOD & DRUG ADMINISTRATION

Get to Know OGD's Office of Safety and Clinical Evaluation (OSCE)

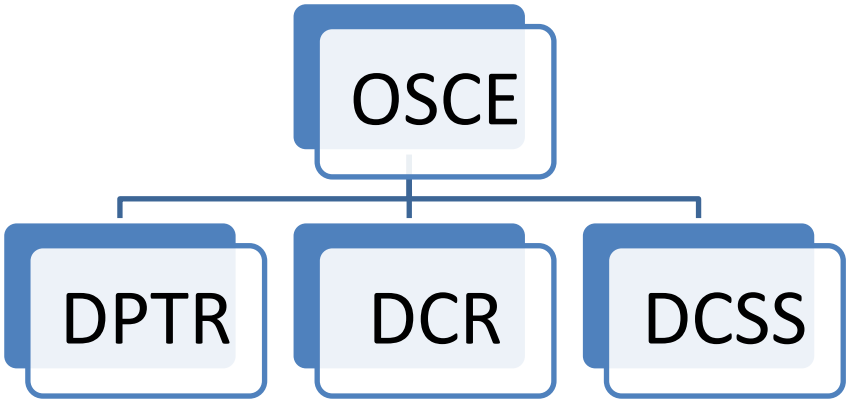
OSCE's Mission

Ensure the American public has **safe** and **therapeutically equivalent** generics:

- Evaluating **clinical and non-clinical** information in support of safety and therapeutic equivalence
- Ensuring compliance with any **safety requirements** such as Risk Evaluation & Mitigation Strategies (REMS)
- Conducting ongoing **safety surveillance** after approval

Who We Are

- Multi-disciplinary staff that are organized in three Divisions that play different roles in support of the Generic Drug Program



Safety profile of generic should be the same as the Reference Listed Drug (RLD)

OSCE: Office of Safety and Clinical Evaluation
DPTR: Division of Pharmacology Toxicology Review
DCR: Division of Clinical Review
DCSS: Division of Clinical Safety and Surveillance

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Division of Pharmacology/Toxicology Review

DPTR

DPTR

- Determines whether **exposure** is **safe**
  - Impurities
  - Excipients
  - Nitrosamines
  - Residual Solvents
  - Extractables/Leachables
- Reviews products **throughout the lifecycle**
  - Controlled Correspondences and Pre-ANDA meetings
  - DMFs and ANDAs, Post-CRL ANDA meetings
  - Prior approval supplements and post-marketing safety
- Works with clinical and quality staff to support OGD mission of safe and therapeutically equivalent generic drugs

CRL: Complete Response Letter
DMF: Drug Master File

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Division of Clinical Review

DCR

DCR

- Support **pre-approval clinical safety**
  - Controlled Correspondence
  - Pre-ANDA meetings
- Evaluate **clinical safety and therapeutic equivalence** of ANDAs
  - Comparative Analyses — Maximum Daily Dose Determinations
  - Comparative Clinical Endpoint Bioequivalence studies
- **Work** with OGD, OSE, and OPQ to address **safety concerns** for proposed generics
  - Pharmacokinetic studies — Citizen Petitions
  - Labeling issues — Suitability Petitions

OSE: Office of Surveillance and Epidemiology
OPQ: Office of Pharmaceutical Quality

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Division of Clinical Safety and Surveillance

DCSS

DCSS

- **Facilitate and coordinate** REMS for ANDAs
- Support **pre-submission clinical safety**
  - Bio-INDs
  - Covered Product Authorization requests
- Support **post-approval clinical safety**
  - Health Hazard Evaluations
  - Relisting Petitions
- **Analyzes** post-market data for ANDA **quality and therapeutic equivalence safety signals**
  - Newly Identified Safety Signals for generic drugs

IND: Investigational New Drug


FDA
We care about enhancing access to generic drugs
WE ARE THE GENERIC DRUG PROGRAM