Development & Approval Process (CBER)

The Center for Biologics Evaluation and Research (CBER) regulates products under a variety of regulatory authorities including the Public Health Service Act and the Food Drug and Cosmetic Act.

Key Resources

- **Investigational New Drug (IND) or Device Exemption (IDE) Process (CBER)**
  (/BiologicsBloodVaccines/DevelopmentApprovalProcess/InvestigationalNewDrugINDorDeviceExemptionIDEProcess/default.htm)
  An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

- **Biologics License Applications (BLA) Process (CBER)**
  (/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/default.htm)
  The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2).

- **510(k) Process (CBER)**
  A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters...

- **Premarket Approval (PMA) Process (CBER)**
  (/BiologicsBloodVaccines/DevelopmentApprovalProcess/PremarketApprovalPMAProcess/default.htm)
  Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in...

- **New Drug Application (NDA) Process (CBER)**
  New Drug Applications (NDAs) are regulated under 21 CFR 314

- **Regulatory Submissions in Electronic Format for Biologic Products**
  (/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm163685.htm)

Spotlight

- **U.S. Food and Drug Administration Statement: The impact of February's inclement weather on Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA) deadlines**
  (/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm200361.htm)

Recalls & Alerts

- **Recalls (Biologics)**
  (/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm)

- **CBER-Regulated Products: Shortages and Discontinuations**
  (/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm)

- **Report a Problem to the Center for Biologics Evaluation & Research**
  (/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/default.htm)
Approvals & Clearances

- Biologics Products & Establishments (/BiologicsBloodVaccines/ucm121134.htm)

Related Information

- Combination Products (/CombinationProducts/default.htm)
- Critical Path Initiative (/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm)

Contact FDA

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