CDER and CDRH: Working together to regulate the development of new stroke therapies

Billy Dunn, M.D.
Division of
Neurology Products
CDER
FDA

Carlos Peña, Ph.D., M.S
Division of Neurological and Physical Medicine Devices
CDRH
FDA

Approval Process

- Both CDER and CDRH are charged with determining safety and effectiveness
  - CDRH: “reasonable assurance that the device is safe and effective for its conditions of use”
  - CDRH: also must contend with “least burdensome provisions”
  - CDER: “substantial evidence of effectiveness”

Approval Process

- Once lead Center is identified (via process of assignment), a consultative or collaborative review may be initiated with another center
  - Consultative review: advice from another center on a specific question or issue
  - Collaborative review: two or more Centers have primary review responsibilities, generally for a defined portion of a submission

Conclusion

- Drug and device regulation and approval is supported by distinct and robust statutory authority
- Investigational drug and device development programs are subject to highly structured regulatory requirements
- Approval of new drugs and devices is guided by a core set of requirements yet maintains a degree of flexibility
- Combination approaches to therapeutic intervention may require the application of multiple regulatory domains