

# CDRH Post-Approval Studies Program

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# Outline

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- Post-Approval Study Principles
- Program Changes
- Impact on Advisory Panel

# Need for Post-Approval Studies

- Address premarket data limitations
- Gather essential postmarket information
  - Longer-term performance including effects of re-treatments & product changes
  - Community performance (clinicians & pts.)
  - Effectiveness of training programs
  - Sub-group performance
  - Outcomes of concern, real & potential
- Balance premarket burdens
- Account for Panel recommendations

# Pre/Postmarket Balance

- Use premarket data to make initial decisions about safety & effectiveness & gain understanding of device risks/benefits
- Use postmarket data to improve our understanding of the risk/benefit profile; disseminate timely safety information &/or take regulatory action as appropriate
- PAS should not be used to evaluate unresolved issues from the premarket phase that are important to initial determination of device safety and effectiveness

# Post-Approval Studies (PAS)

- Postapproval requirements can include “continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.” 21 CFR 814.82 (a) (2).

# Legal Authority

## ■ Title 21 Section 814.82

(a) FDA may impose post-approval requirements at the time of approval of the PMA or by regulation subsequent to approval and may include:

(2) Continuing evaluation and reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state the reason and the number of patients to be evaluated.

(9) Other requirements as FDA determines necessary to provide (continued) reasonable assurance of the safety and effectiveness of the device.

# Internal Evaluation of CoA program

- 1998 through 2000: 127 PMAs approved with 45 CoA orders.
- CDRH had limited procedures for tracking progress or results

# Program Goals

- Help to assure continued device safety & effectiveness
- Obtain useful & timely post-market information in the “real world” as the device enters the market
- Better characterize the risk/benefit profile
- Add to our ability to make sound scientific decisions

# Program Oversight

- Transfer post-approval program from ODE to OSB (1/1/05)
- Develop & institute automated tracking system for post-approval study commitments
  - Acknowledge receipt of study reports
  - Follow-up when reports not received

# Role of Epidemiologists - Premarket

- Develop a “Postmarket Plan”
- Lead development of well-formulated & essential post-market questions
- Lead design of PAS protocol and work interactively with fellow reviewers and sponsor prior to panel meeting to assemble PAS protocol.
- Provide input at Panel meetings
- Finalize PAS protocol with sponsor prior to or at the time of Approval Order.
- Collaborate with PMA team throughout

# Postmarket Plan (PMP)

- Epidemiology lead
  
- Comprehensive approach
  - Study progress review
  - MDR analysis
  - Literature review and assessment
  - External databases exploration/analysis
  
- 6- month updates to the review team

# Role of Epidemiologists- Postmarket

- Lead evaluation of study progress & results
- Provide PMP updates to ODE/OIVD

# Draft Guidance: Procedures for Handling Post-approval Studies Imposed by PMA Order

- Purpose:
  - Provide recommendations on information format & content
  - Increase transparency of CDRH approach
- General information :
  - Sponsor, product, submission type
- Study information:
  - Status
  - Changes
  - Interpretation

# Draft Guidance

- Study information on web:
  - Sponsor & product;
  - Dates
  - Commitment & status
- Advisory Panel update:
  - Study status or outcomes
  - Analysis & evaluation
- Other options (including enforcement)

# Least Burdensome Approach

- Least burdensome principles apply
- They are acknowledged in FDA guidance:  
“...concept should be integrated in pre-market activities, as well as post-market activities as they relate to the pre-market arena”
- The “way” to least burdensome is to discuss pre/postmarket balance as early as possible in the approval process

# Benefits of the Change

- Better designed Post-Approval Studies
  - Begin to address postmarket issues early
  - Experts in observational studies will take a lead
- Tracking of all PAS
- More complete postmarket information being collected and organized by OSB staff to feed back to premarket reviewers

# Impact on Advisory Panel

- During approval process: we will attempt to lay out important post approval public health questions and possible approach for panel consideration
- During postmarket: FDA or industry will update the Advisory panel on the progress and results of CoA studies for approved devices

# Vision for the Future

- Important postmarket questions are addressed
- Studies are realistic & founded on good science
- Studies are timely, accurate, & provide useful results
- Reports are clearly identified & effectively tracked
- Stakeholders are kept apprised
- Collaboration is stressed throughout
- Enforcement options are rarely used