CDER Public Meeting

Supplements and Other Changes to an Approved Application

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Welcome

- Important meeting
- 314.70 and postmarket changes essential to determining how modernize CMC regulation
- Appreciate participating
- Meeting to listen to public about possible revisions to 314.70
- “Housekeeping”

Interpretation

- Sign language interpreters on hand today for those individuals needing to make use of that accommodation
- Is there anyone who needs the interpreters?

Record

- Transcript will be available
- Comments can be submitted directly to the docket
  - 2006N-0525
- DVDs of recorded meeting will be made available from “FDALive”
  - Order them just outside this room

Purpose of Public Meeting

- Solicit comments on issues that should be considered if FDA decides to propose revisions to 314.70 – currently evaluating how we would make revisions – want your input
- Interested in weaknesses, strengths, etc., in current 314.70
- Interested in hearing suggestions for possible changes that will improve industry's ability to provide high quality products
- Interested in public's concerns regarding changes
- Open - FDA will consider presentations from this public meeting and from information submitted to the docket

FDA's Vision for Change

- Allow for some manufacturing changes to be made without prior FDA approval based on
  - Process and product understanding which leads to risk-based approaches to change
  - Use the firms' internal change control system
- Reduce the number of postmarket supplements
- Manufacturers would still be responsible for ensuring product quality

Questions

- Is there value in the Agency moving toward a more risk-based and quallty systems approach to regulating postapproval CMC changes? What are the advantages and disadvantages?
- Would a revision to 314.70 to provide more flexibility to postappoval CMC changes provide the same level of protection to the public with respect to ensuring safety and efficacy of products?
- Would revising 314.70 change the regulatory burden on the pharmaceutical industry.? If so, how would the burden change? Would there be a greater burden?
- Would reducing the prescriptiveness of 314.70 provide manufacturers with greater regulatory flexibility? What would that flexibility look like?

Program

- FDA
  - Discuss issues regarding 314.70 in current regulatory scheme and in proposed new CMC assessment regulatory processes
- Industry Organizations
  - Industry representatives to provide consolidate thoughts from their constituents on possible revisions
- People responding to the FR Notice
  - Speakers must have registered ahead of time and submitted summaries of their presentations