Abuse Deterrent Products:Next Steps

Tufts Health Care Institute Program On Opioid Risk Management: **Guidelines for the Development of Abuse-Deterrent Opioid Formulations**

November 9-10, 2006

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Assuming that Abuse Deterrent products are a good idea…

- What incentives would stimulate their development?
- What steps would then ensure their availability?

Proposed incentives

- Exclusivity
- Reimbursement
- Tax credits for clinical trials
- Clearly articulated ground rules (Guidance) and protocol assistance
- Fast track status
- Priority review
- Meaningful Labeling

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"Prescription Drug Abuse: What is being done to address this new Drug Epidemic?"

- Hearing: Subcommittee on Criminal Justice, Drug Policy and Human Resources July 26, 2006
- Three questions for FDA
  - "if the FDA has responded to Congress's year-old request for a report on how the agency might handle priority review of abuse-resistant formulations of prescription controlled drugs"
  - "Why hasn't FDA provided guidance on this important matter?"
  - "to provide specific legislative recommendations for the reauthorization of PDUFA that will provide incentives for developing, and allow for the accelerated approval of, abuse-resistant forms of highly abused drugs"

Making your voice heard at FDA

- Comment on proposed Regulations
- Comment on proposed Guidance
- Submit Citizen’s Petition

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Participation in Guidance Development

Under Section 701(h)(1)(A) of FDAMA

May include:

- Suggestions for areas of guidance development
- Submission of drafts to FDA for consideration
- Suggestions about revisions of an existing guidance document
- Submission of comments on an annual list of possible topics for future FDA guidance development
- Submission of comments on specific proposed and final guidance documents

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Suggestions for areas of guidance development

- http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA

[**Dockets Open for Comment**]

Docket Number & Title: 2004N-0234 - Annual Guidance Agenda

FR Type: Notice

Action: Other

Comment Period End Date:08/31/07

View FR Document for this Docket

submit comments

Submission of drafts of guidance documents to FDA

If you want FDA to draft a guidance document on a particular issue you should:

- Contact the Center (i.e., CDER) or Office (Office of the Commissioner) that is responsible for the regulatory activity covered by the guidance document
- Include a statement of why the new document is necessary

Question for consideration

- Why is the proposed guidance document necessary?

Citizen's Petition

- …to request the commissioner of FDA to (issue, amend, or revoke a regulation or order, or to take or refrain from taking any other administrative action

Citizen's Petition: Possibilities

- To draw upon the collective knowledge of experts in the area of analgesia, addiction, abuse liability assessment, diversion control, epidemiology (etc) to develop a series of guidance documents that provide a specific framework for development and labeling of abuse-deterrent products.
- To designate abuse-deterrent products aimed at lessening the burden of Prescription Drug Abuse for "fast track" and assign a "priority review" (6 months) upon NDA submission.
- Develop a credible plan for a legislative remedy that would provide greater incentives for innovation in the area of abuse-deterrent opioid formulation development

Guidances: further possibilities

- Developing an Abuse-deterrent formulation
- CMC (subsection or companion guidance)
  - Specifications for testing extractability, tamperability and separation
- Labeling (subsection or companion guidance)
  - Guidance for obtaining specific implicit claims in product labeling related to abuse liability and tamper-deterrence
- Others?

MAPP 4000.2 Developing and Issuing Guidances

- Communication of new policies through informal mechanisms such as speeches and letters to firms must be avoided until a policy is appropriately formulated, documented, and cleared…Repeated questions about a particular area may signal the need to develop clarifying policy and guidance for that area
- CDER maintains a Guidance Agenda
- Agency may solicit or accept early input on the need for a new…guidance, or assistance in the development of a particular guidance document from individual governmental and nongovernmental groups.
- The Agency may participate in meetings with these various parties to obtain each party's views on priorities for developing guidance documents.

MAPP 4000.2

- Level approach to guidance development (Level 1—unusually complex scientific issues, highly controversial issues, changes in policy)
- Level 1 requires public input (usually solicited prior to implementation)
  - NOA
  - Post draft guidance on CDER home page

Drafting a Guidance

- Specific protocol has been developed for initiating, drafting and clearance within FDA
- Template available only on CDER Intranet
- Guidances are developed to reflect FDA policy
- FDA has intentionally not included specific elements of Good Guidance in the regulations
- Guidance is nonbinding but there must be adequate cause to deviate from the written guidance as it reflects “current policy”

Proposal

- Provide outline for elements that are necessary for development of an abuse deterrent formulation
- Consider the elements that FDA considers when approving a drug and outline these systematically as they relate to new abuse-deterrent formulations
  - CMC (extraction, physical tampering, chemical tampering, separating components)
  - Efficacy (demonstration of effectiveness at various regimens and with transition from a traditional formulation—issues of LOE and withdrawal)
  - Safety (preclinical toxicology and clinical—demonstrating safety of new excipients, for example)
  - Biopharmaceutics (DDI, alcohol interaction, bioavailability by various routes of administration if extracted)
  - Abuse liability (compared with traditional formulation)
  - Labeling (implicit claims)