U.S. Food and Drug Administration

Generic Drug User Fee Amendments of 2012

http://www.fda.gov/gdufa

Guidance for Industry on *Controlled Correspondence Related to Generic Drug Development*

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Generic Drug User Fee Amendments of 2012

- The Generic Drug User Fee Amendments of 2012 (GDUFA): designed to bring greater predictability and timeliness to generic drug review by enabling FDA to assess user fees to fund critical and measurable improvements to FDA's generic drug program.
- FDA and generic industry negotiated a Commitment Letter with agreed-on metrics to achieve GDUFA goals.

GDUFA Performance Metric Goals

FDA committed to certain time periods (goal dates) within which FDA must respond to "controlled Correspondence" (CC):

- 70 percent of CC in 4 months from date of submission in FY 2015.
- 70 percent of CC in 2 months from date of submission in FY 2016.
- 90 percent of CC in 2 months from date of submission in FY 2017.
- If the CC requires input from the clinical division, one additional month will be added to these goals.

GDUFA Commitment Letter on CC

- If CC raises an issue that is the same as or related to the issue or question that is the subject of a pending citizen petitions, or petitions for stay or reconsideration, goals will apply from the date FDA issues response.
- Definition of CC: “FDA’S Office of Generic Drugs provides assistance to pharmaceutical firms and related industry regarding a variety of questions posed as ‘controlled documents.’ ...”

Guiding Principles of CC Guidance Development

- GDUFA Commitment Letter references OGD's historical practices – reflects intent not to "reinvent the wheel"
- Supports principles identified in Commitment Letter: safety, access, and transparency
- Intent: to provide practical guidance for industry and FDA

Overview of Guidance

Guidance provides information regarding:

- FDA's historical practices with respect to CC
- CC-related provisions of Commitment Letter
- Definition of a CC
- How to submit a CC
- Information on Communications from FDA

OGD Historical Practices

FDA website provided “Recommendations for Improving Submissions of a ‘Controlled Correspondence’ to the Office of Generic Drugs”

- Identified process as one for “pharmaceutical companies and related industry”
- Included recommendations on format and submissions
- Provided detail on specific types of inquiries, e.g., acceptable formulations

What is a CC?

Definition in guidance – provides substantive framework for CC process:

> ***A correspondence submitted to the agency, by or on behalf of a pharmaceutical company or related industry, requesting information on a specific element of generic drug product development***

What is a CC (cont.)

Guidance on specific types of CC

- CC raising same issue as citizen petition, request for reconsideration or stay – goal dates determined by year of submission, and run from date of FDA response to CC
- CC inquiry on matters still under consideration by FDA

Alternative Mechanisms for Certain Inquiries

Information on alternative mechanisms to submit inquiries for which the CC process is less appropriate

- Pre-ANDA meetings
- Submissions to Regulatory Science Initiative

What is a not CC?

Inquiries outside scope of CC

- Topics outside scope: e.g., pending ANDAs, OGD administrative practices, inquiries on non-U.S. approved products, general questions
- Entities outside scope: e.g., private citizens, financial firms, public advocacy groups (directs these parties to CDER Drug Info)

What is not a CC? (cont.)

Requests for product-specific guidance

- FDA will continue product-specific guidance process; allows for transparency, public process
- Consistent with GDUFA regulatory science initiative
- Goal dates inconsistent with existing product-specific priority setting process

What is not a CC? (cont.)

Requests for review of clinical protocols:

- Historically not CC
- Time- and resource-intensive; often involve cross-discipline consideration
- FDA will respond as expeditiously as practicable

Meeting Requests: serve different purpose than CC, and involve different materials

How to Submit a CC

Guidance provides practical recommendations on how to submit CC under GDUFA:

- CC under GDUFA may be submitted electronically, from corporate address, to genericdrugs@fda.hhs.gov
- No paper, no duplicates, no email to individual FDA employees

Practical Recommendations on What to Include in a CC under GDUFA

- Specific information about requestor
- Concise statement of inquiry
- Any relevant reference listed drug info
- Any previous CC on same issue
- Prior relevant research
- Recommended review discipline

What to Include for Certain CC

- Requests concerning acceptability of inactive ingredients
- Requests for Q1/Q2 formulation assessment
- Requests seeking information related to more than one review discipline, e.g., BE and Labeling, should be submitted separately

FDA Communications to Requestors

- Upon receipt of CC, FDA will send email :
  - Confirming inquiry is CC, assign tracking number, receipt date; or
  - Notification that inquiry is not CC, or lacks sufficient info
- Notification of missed goal date
- Substantive response to inquiry via email

Comments on the Draft Guidance

- FDA received comments from 10 entities to public dockets for the draft guidance and GDUFA Policy Development Part 15 hearing
- Comments were submitted by:
  - Pharmaceutical companies
  - Industry trade associations

Comments on the Draft Guidance (cont.)

- Requests to include product-specific guidances, clinical protocol reviews in CC process
- Requests to revisit the cap of three inactive ingredients/formulations/strengths per request
- Requests to keep CC that raise complex questions open until resolved

Comments on the Draft Guidance (cont.)

- Common comments:
  - Requests for status updates and target action dates for missed goal dates
  - Requests for enhanced communication (content and frequency)

Revisions to the Draft Guidance

- Highlights:
  - Clarification of important terms, e.g., “related industry”
  - Clarification on limit of three formulation reviews at any given time
  - Revised recommendations on “open/complex policy” issues
  - Enhanced communication

Revisions to the Draft Guidance (cont.)

- Enhanced communication:
  - Letter of Interest – Sent for legacy controls to confirm the submitter still wants response
  - Missed goal date – To be sent for controls to acknowledge a goal date has been missed

Revisions to the Draft Guidance (cont.)

- Enhanced communication:
  - Missed goal date and complex issue – To be sent for controls to acknowledge a goal date has been missed due to a complex/unresolved issue
  - Notification of hold due to a pending citizen petition

Questions?

Email genericdrugs@fda.hhs.gov