Overview of Controlled Correspondence Process

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Discussion Overview

- Introduction
- What is a Controlled Correspondence (CC)
- What is not a CC
- Submitting a CC
- CC Tips
- Resources & Questions

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 Commitment Letter: CC Performance Metric Goals

FDA committed to certain time periods (goal dates) within which FDA must respond to 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.

What is a CC?

- Definition in final guidance:

  A correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry, requesting information on a specific element of generic drug product development.

What is not a CC?

- Topics outside scope: e.g., pending ANDAs, OGD administrative practices, inquiries on non-U.S. approved products, general questions
- BE guidance requests*
- Protocols*
- Meeting Requests*

*Still submitted to the same email address as CC: genericdrugs@fda.hhs.gov

How to Submit a CC

- CC under GDUFA may be submitted electronically, from a corporate address, to genericdrugs@fda.hhs.gov
  - Only those submitted electronically will receive a GDUFA goal date
- No paper, no duplicates, no email to individual FDA employees

What to Include in a CC

- Specific information about requestor
  - Include a Letter of Authorization if submitted through an Agent with each communication
- Concise statement of inquiry
- Any relevant reference listed drug info
- Any previous CC on same issue
  - Include a copy of the previous CC and the response letter
- Prior relevant research
- Recommended review discipline

What to Include for Certain CC

- Requests concerning acceptability of inactive ingredients
  - Max of 3 Inactive ingredients

Inactive Ingredient (IIG)	Proposed Level
A	20mg
B	20mg
C	20mg

  - **OR** Max of 3 Levels

Inactive Ingredient (IIG)	Proposed Level
A	20mg
	30mg
	40mg

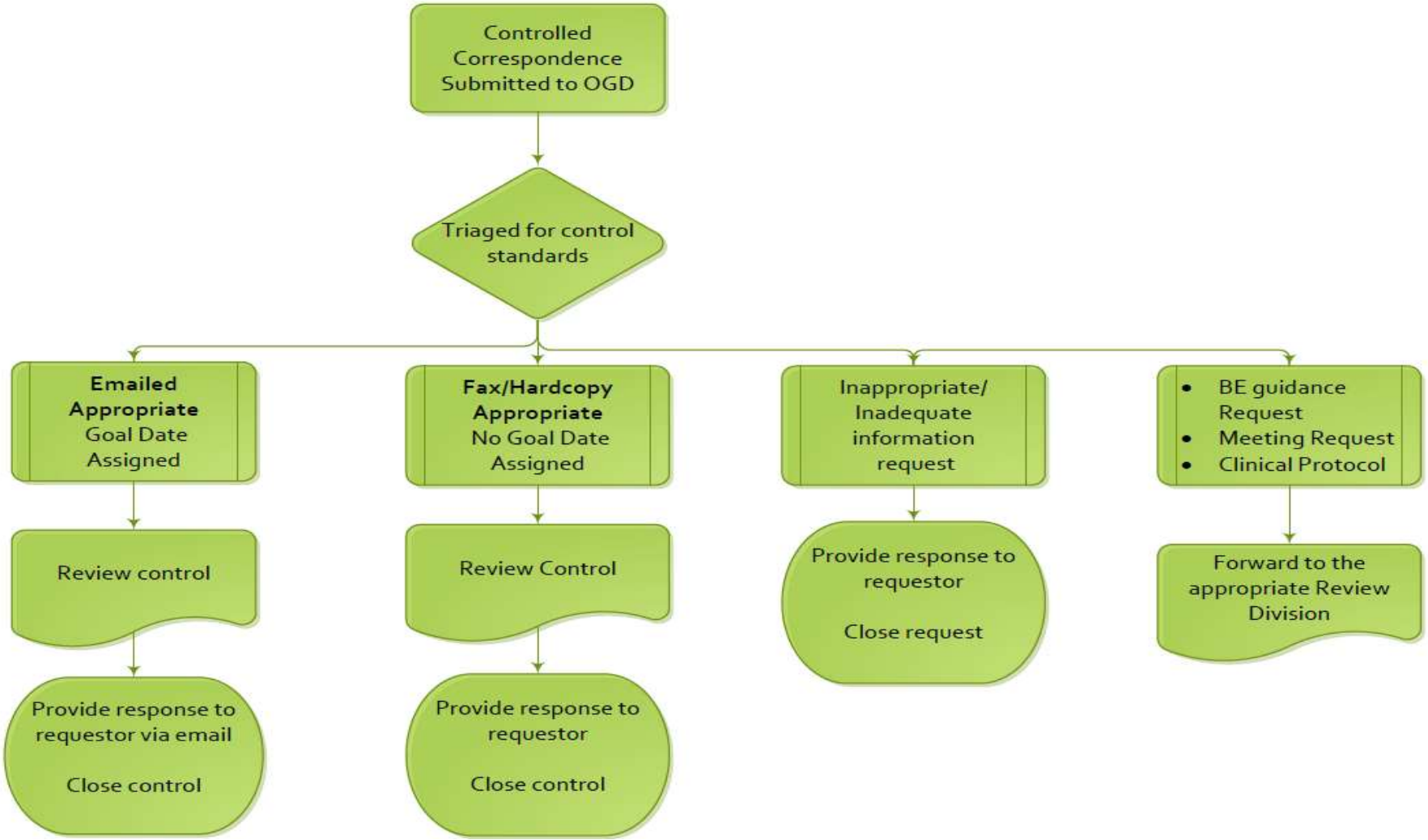
What to Include for Certain CC

- Requests for Q1/Q2 formulation assessment
  - Max of 1 strength per CC
  - Max of 3 formulations per CC
- 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 one of two emails:
  - Confirming inquiry is CC, assign tracking number, receipt date; or
  - Notification that inquiry is not CC or lacks sufficient info
- Substantive response to inquiry via email
- Notification of missed goal date
- Notification that the CC is on hold due to a pending Citizen Petition/Petition for Reconsideration/Requests for Stay
- FDA will not respond to status inquiries prior to the assigned goal date

Controlled Correspondence Process



CC – Tips

- Ensure contact information is up-to-date
- Response will only be sent back to the original email
- Any inquiry sent to GenericDrugs@fda.hhs.gov on behalf of a foreign firm should be submitted through their US Agent
- Include the ANDA number for any questions related to a pending or approved ANDA
- New control number will be issued for every control

CC – Tips cont.

- Recommend that the subject line of the email contain a brief description of the control and the drug name

Example subject line format: Controlled Correspondence: 'DRUG PRODUCT & RLD No.' – 'BRIEF DESCRIPTION OF INQUIRY'

- i.e. Controlled Correspondence: Amoxicillin Capsules 500mg RLD A061926 – IIG evaluation of Lactose
- i.e. Controlled Correspondence: Clarification of Stability Q&A – E.Q1.A1

CC – Tips cont.

- All requests/inquires related to controlled correspondence must come through the GenericDrugs mailbox. Including:
  - Request for the status of a controlled correspondence
  - Request for clarification of a response to a controlled correspondence
  - Request for an explanation of why something was deemed not appropriate for a controlled correspondence.

CC – Tips cont.

Submit the following to the genericdrugs@fda.hhs.gov email box:

- Controls
- Meeting Request
- Protocols
- BE Guidance

To Do's

- Include RLD information
- Status of my CC – past 60 days

Not - To Do's

- Include tables in the content of your emails
- Send CC from general, personal email account
- Send CC directly from a foreign firm
- Send the same questions to multiple offices
- Send waiver request as a CC – will not pre-review
- Send PharmTox data for review – will not pre-review

Resources

OGD Website:

- http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm142112.htm

Controlled Correspondence Final Guidance Link:

- http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm411122.htm

Questions?
Contact

Generic Drugs Mailbox

- genericdrugs@fda.hhs.gov

ANDA Filing status:

- ANDAFiling@fda.hhs.gov

General Questions: CDERSBIA@fda.hhs.gov