

# Controlled Correspondence Program Updates under GDUFA III

#### Marcia D. Fields, PharmD

Lieutenant Commander, U.S. Public Health Service Office of Regulatory Operations, Office of Generic Drugs CDER | U.S. FDA

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## Learning Objectives



- Define the types of controlled correspondence
- Describe elements of acceptable correspondence
- Devise an outline for best practices
- Confirm understanding resources and contacts

#### Poll Question #1



Have you previously attended a SBIA conference that included information related to controlled correspondence?

A. Yes

B. No

#### Poll Question #2



Are you aware there is a Draft Guidance for Industry Controlled Correspondence Related to Generic Drug Development published in December 2022?

A. Yes

B. No

#### **Definitions**



- Controlled Correspondence
- Level 1: previously known as Standard
- Level 2: previously known as Complex
- Clarification of Ambiguity

## Level 1 Controlled Correspondence



- Before abbreviated new drug application submission
- After product-specific guidance teleconference
- After complete response letter or tentative approval
- Post approval

## Level 2 Controlled Correspondence



- Clinical content
- Alternative bioequivalence (BE) approach
- Consultation with another office or center
- Covered product authorization

## Clarification of Ambiguity



 Ambiguity in the controlled correspondence response means the controlled correspondence response or a critical portion of it merits further clarification

### **Quick Review**



- Definitions
- Post conference evaluation
- Resources

# Examples of What is **not** a Controlled Correspondence



- General Questions
- Outside of Scope
  - No U.S. approved Reference Listed Drug

# What to Include in a Controlled Correspondence



- Documents on corporate letterhead
- Complete contact information
- Letter of Authorization (if submitted by authorized agent)
- Reference listed drug (RLD)

# What to Include in a Controlled Correspondence



- Previous related controlled correspondence
- Prior relevant research
- Recommended review discipline
- Concise statement of inquiry
- Statement that the controlled correspondence is related to either a potential or actual ANDA submission to OGD

# Inactive Ingredient Evaluation Controlled Correspondence

- Exceed levels in Inactive Ingredient Database
- Three inactive ingredients

Inactive Ingredient (IIG)	Proposed Amount (mg)
Α	20
В	20
С	20

Three proposed amounts

Inactive Ingredient (IIG)	Proposed Amount (mg)
Α	20
	30
	40

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## Inactive Ingredient Evaluation Controlled Correspondence



- Highest proposed amount in range
- Only inactive ingredients in question
- No PharmTox data
- Separate: Different routes of administration

# Q1/Q2 Evaluation Controlled Correspondence



- One strength per controlled correspondence
- Three formulations per controlled correspondence
- Avoid ranges
- Composition should reflect ANDA submission

# Controlled Correspondence after Issuance of Complete Response Letter (CRL)



- Include a copy of the CRL
- Reference to the specific deficiency in the CRL
- Proposed responses to deficiencies should be submitted to the ANDA

# Inquiries Related to a Specific Pending ANDA



- New strength
- New package
- Advice to address deficiency in CRL
- Feedback after product specific guidance Tcon
- Covered Product Authorization (CPA)

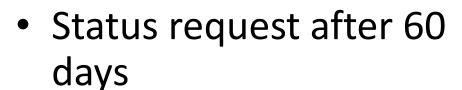
#### FDA Communications to Requestors



- Controlled Correspondence Acknowledgment
- Substantive response
- Missed Goal Date
- Status Request

Guide to Distinguish **Meeting Request** versus **Submitting** Controlled Correspondence





- FDA will not pre-review BE Waiver Requests
- inquiry in a controlled correspondence ≠ inquiry in meeting request





# Related to Clarification of Ambiguities

- Letter of Authorization
- 7 calendar days
- No Q1/Q2 formulation explanation



# Content Submissions

#### **Portal**

- U.S. agents
- Use a corporate email address
- Ensure consistency
- Include ANDA
- Control numbers issued



# Content Submissions Portal

- Invalid controlled correspondence
- Cover letter dated within 7 days of receipt
- 1 year Letter of Authorization (LOA)

## Challenge Question #1



How long should you wait to receive acknowledgment that the controlled correspondence was accepted or not?

- A. 30 days
- B. 7 days
- C. 60 days
- D. 120 days

## Challenge Question #2



After what time period may you request a status if you have not yet received a substantial response/review from the Agency?

- A. 7 days
- B. 21 days
- C. 30 days
- D. 60 days

#### Points of Contact



- General Questions: <u>CDERSBIA@fda.hhs.gov</u>
- For technical support with Portal: <u>EDMSupport@fda.hhs.gov</u>
- Generic Drugs Mailbox genericdrugs@fda.hhs.gov
- ANDA Filing status: <u>ANDAFiling@fda.hhs.gov</u>
- Pre-ANDA Development Meetings:

PreANDAHelp@fda.hhs.gov

#### Resources



• Controlled Correspondence Draft Guidance Link (December 2022):

https://www.fda.gov/media/164111/download

 GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter)

https://www.fda.gov/media/153631/download

#### Resources



OGD Website:

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

GDUFA III Webpage:

https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii

 Recorded Presentation Highlighting Important GDUFA III Changes Related to Controlled Correspondence (October 2022)

https://www.youtube.com/watch?v=wfsb6Vvn0eg

#### Resources



- Instructions for Creating a Portal Account: https://www.fda.gov/media/128774/download
- Portal Link: <a href="https://edm.fda.gov">https://edm.fda.gov</a>

 FAQs related to Portal <u>https://cdernextgenportal.fda.gov/CDER\_FAQ\_Page</u>

## Summary



- Characterized correspondence
- Distinguished non-controlled correspondence
- Highlighted tips for success
- Aspects of invalid controlled correspondence

