

OFFICE OF REGULATORY POLICY

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Submitting Issues/Documents to the Office of the Chief Counsel (OCC)  
for Legal Review, Comment, or Clearance

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**PURPOSE**

- This MAPP establishes the policies and procedures in the Center for Drug Evaluation and Research (CDER) for forwarding documents and questions to the Office of Chief Counsel (OCC) for review, comment, or clearance. It revises and replaces a MAPP with the same title, MAPP 4513.1, dated 5/31/00, to reflect organizational changes in the Office of Regulatory Policy (ORP).

**BACKGROUND**

- Center staff routinely seek both informal and formal advice and request clearance of documents from OCC.
- Because of the volume of requests and the historical limitations on OCC resources, CDER now identifies its work priorities so that OCC can respond to CDER requests.
- Accordingly, the Center is establishing this MAPP for tracking and prioritizing requests for OCC advice and clearance.
- This MAPP does not apply to informal requests for advice conveyed by telephone, E-mail, or face-to-face that can be answered immediately and that do not involve legal research or document review.

**DEFINITIONS**

- **Concurrent Clearance:** Obtaining clearance by OCC staff.
- **Final Clearance:** Clearance by OCC management or designee.

- **2-Week Goal Date:**
  1. Response from OCC is needed within 2 weeks of the date sent.
  2. The request is for final clearance of a document directly related to a provision of the U.S. Food and Drug Administration Modernization Act of 1997.
- **30-Day Goal Date:**
  1. Response from OCC is needed within 30 days of the date sent.
  2. The due date of the request is directly linked to a statutory or regulatory time frame.  
  
or
  3. OCC's response will directly affect a decision by the Center on a pending application.
- **60-Day Goal Date:** All other requests.
- **Ongoing Advice:**
  1. Legal advice is needed on a long-term basis.
  2. Legal advice is needed that covers a particular issue not directly related to any one application, regulation, citizen petition, or any other action.
  3. If review of a particular document is requested, it is to be separately tracked with a goal date as specified above.

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**POLICY**

- All documents sent to OCC for comment, review, or clearance should be faxed, E-mailed, or hand carried to the assistant of the Deputy Chief Counsel for Program Review, and must be accompanied by an *OCC Tracking Information Form* (see Attachment A) with a copy to the ORP Project Manager.
- Requests for legal advice or opinions that cannot be answered immediately by phone and that require research or document review by OCC also should be accompanied by an *OCC Tracking Information Form*.

**RESPONSIBILITIES AND PROCEDURES**

- **Originators of requests will:**
  1. Complete the *Project Information* section for the *OCC Tracking Information Form* (see Attachment A). This form is available electronically on the Internet at <http://cdernet/orp>.
  2. Obtain Division or Office level clearance.
  3. Ensure that the goal date has concurrence from the CDER Associate Director for Policy for any request submitted with a 2-week or 30-day goal date. To receive concurrence from the CDER Associate Director for Policy, please E-mail the CDER Associate Director for Policy (currently Jane Axelrad) and cc: the ORP Project Manager (currently Tawni Brice) with an explanation of the project and the reason for requesting a faster review time.
  4. Have the completed form with the material to be reviewed and any pertinent background information faxed, E-mailed, or hand carried to the Deputy Chief Counsel for Program Review's assistant.
  5. Forward a copy of the form to the ORP Project Manager.
- **CDER Associate Director for Policy will:**
  1. Concur or not concur with all goal dates for all issues and/or documents going to OCC with a 2-week or 30-day goal date.
  2. Meet periodically with OCC to discuss and adjust Center priorities for OCC work. The goal dates will be modified as necessary through coordination and agreement between OCC and CDER based on current Center priorities.
  3. After consultation with other CDER managers, prioritize the Top 20 items in OCC for review on a monthly basis.
- **ORP Project Manager will:**
  1. Fill in the *Tracking Numbers* section on the *OCC Tracking Information Form*.
  2. Ensure that all 2-week and 30-day goal dates on projects have been cleared by the CDER Associate Director for Policy.
  3. Notify the assistant for the Deputy Chief Counsel for Program Review promptly by E-mail of any new 2-week and 30-day goal dates that have been cleared.
  4. Enter the appropriate information into the COMIS tracking system.

5. Maintain the COMIS tracking system and provide regular reports to CDER and OCC staff.
  6. Ensure that CDER originators of requests and OCC are aware of goal dates.
  7. Archive all *OCC Tracking Information Forms*.
- **OCC will:**
    1. Refuse to accept any requests from CDER unless they are accompanied by an *OCC Tracking Information Form*.
    2. Enter the assigned attorney's name into the COMIS tracking system.
    3. Review the document and/or issue and comment on the document, clear the document, or respond to the request for advice. Consult with CDER originator of requests, as appropriate.
    4. Enter the action taken and date completed in the COMIS tracking system.
    5. Fill in the *OCC Information* section on the *OCC Tracking Information Form* and forward a copy of the completed form to the ORP Project Manager.
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**EFFECTIVE DATE**

This MAPP is effective on the date of publication.

**ATTACHMENT A**

**CENTER FOR DRUG EVALUATION AND RESEARCH  
OCC TRACKING INFORMATION FORM**

**TRACKING NUMBERS**

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<b>COMIS NO.</b>	<b>FRDTS NO. (If applicable)</b>	<b>CATEGORY NO.</b>
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**PROJECT INFORMATION**

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<b>CDER CONTACT PERSON</b>	<b>PHONE NO.</b>	<b>FAX NO.</b>
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**DATE SENT TO OCC**

**GOAL DATE** \_\_\_\_\_ *2 Weeks* \_\_\_\_\_ *30 days* \_\_\_\_\_ *60 days* \_\_\_\_\_ *Ongoing Advice*  
Note: All standard requests should have a 60-day goal date. Those requesting a 2 week or 30-day goal date, must get prior approval through Jane Axelrad (E-mail Axelradj and cc: Bricet) prior to submitting a request to OCC. Refer to MAPP 4140.5. Please fill in the actual goal date on the appropriate line above.

**PROJECT NAME**

**PROJECT DESCRIPTION**

**PROJECT TYPE**

_____ <i>Federal Register</i>	_____ <i>Guidance</i>	_____ <i>Question/Opinion</i>
_____ <i>Citizen Petition</i>	_____ <i>Letter</i>	_____ <i>Ongoing Advice</i>
_____ <i>Suitability Petition</i>	_____ <i>Memo</i>	_____ <i>Other</i>

**REQUESTED ACTION**

_____ <i>Meeting Request</i>	_____ <i>Concurrent Clearance</i>	_____ <i>Other</i>
_____ <i>Review and Comment</i>	_____ <i>Final Clearance</i>	

**OFFICE/DIVISION DIRECTOR'S SIGNATURE**

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**OCC INFORMATION**

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<b>DATE RECEIVED</b>	<b>DATE COMPLETED</b>
<b>ASSIGNED ATTORNEY</b>	<b>ACTION TAKEN BY OCC</b>
<b>OCC SIGNATURE</b>	_____ <i>Cleared</i> _____ <i>Comments</i>
	_____ <i>Not Cleared</i> _____ <i>Other</i>

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