DOCUMENT DEVELOPMENT AND MANAGEMENT

Submitting Proposals to the Office of Regulatory Policy (ORP) for Early Analysis of Rulemaking Initiatives

CONTENTS

PURPOSE

- This MAPP establishes the policies and procedures in the Center for Drug Evaluation and Research (CDER) for submitting proposals to the Office of Regulatory Policy (ORP) for rulemaking consideration. It allows early analysis of regulatory initiatives to identify special concerns at the preliminary stages so timely decisions can be made on the critical aspects of the project.

  This MAPP does not apply to all rulemaking initiatives in the Division of Over-the-Counter Drugs (OTC). It does not apply to routine OTC monograph rulemaking documents. The MAPP does apply to non-monograph rulemaking documents (e.g., OTC labeling rulemaking) and rulemakings that may involve other government agencies (e.g., the Environmental Protection Agency for sunscreen/insect repellant rulemaking).

BACKGROUND

- Center staff routinely submit proposals for regulations and guidances to ORP and request support for regulatory initiatives. To ensure that ORP can respond more effectively to rulemaking requests, CDER now requires written proposals to help identify critical aspects of proposed regulatory initiatives. Accordingly, the Center is establishing this MAPP for tracking and prioritizing requests for ORP support for rulemaking initiatives.

POLICY

- All rulemaking project proposals sent to ORP for comment or review must be accompanied by a copy of the *Regulations Project Proposal Information Form* (see Attachment A) and

faxed, e-mailed, or hand carried to the ORP Project Manager (HFD-7), and the office of the Director, Division of Regulatory Policy (DRP) II (HFD-7).

RESPONSIBILITIES AND PROCEDURES

- **Originators of requests will:**

  1. Complete the *Regulations Project Proposal Information Form* (see Attachment A). [NOTE: This form is available electronically on the common shared drive: x:/offices/ocd_io/forms/regproposal.doc or on CDERNET at http://cdernet.cder.fda.gov/ocd/index.htm].

  2. Obtain Division- or Office-level concurrence.

  3. Send the completed form with the material to be reviewed and any pertinent background information to the ORP Project Manager with a copy to the Director, DRP II (HFD-7). The materials can be faxed, e-mailed, or hand carried.

- **Director, DRP II, will:**

  1. Assign the project to an ORP staff member.

  2. Track the progress made on the regulatory initiative.

- **Assigned ORP Staff will:**

  Evaluate the request, in consultation with the Director, DRP II and the Associate Director for Policy, and provide feedback to the originator in a timely fashion.

- **CDER Associate Director for Policy will:**

  1. In conjunction with the Director, DRP II and the assigned ORP staff person, determine the appropriate response to the proposal.

  2. Meet with the ORP Division Directors periodically to assess the progress and continued appropriateness of the project.

- **ORP Project Manager will:**

  1. Enter the appropriate information into the COMIS tracking system when the request comes in to ORP.

  2. Maintain the COMIS tracking system and provide regular reports to CDER management on the status of regulatory projects.

3. Ensure that CDER originators of requests and ORP staff develop mutually agreed upon goal dates.

4. Archive all *Regulations Project Proposal Information Forms* in ORP.

EFFECTIVE DATE

This MAPP is effective on the date of publication.

ATTACHMENT A

REGULATIONS PROJECT PROPOSAL INFORMATION FORM

ADMIN	Name		Organization:		Phone # and Email:	
	Date:		ORP Contact (if any):		Concurrence from Division Director or above:	
ISSUE	What is the issue to be addressed?					
	What would the regulation accomplish?					
	What is the urgency of the project? Is there a deadline?					
PROJECT TYPE	Is your proposal a necessity or preference?					
	Could the first step be a guidance?					
	How much voluntary compliance would you expect with a guidance?					
	Does your proposal establish a new requirement? If it modifies an existing requirement, which one?					
	Should industry be allowed some flexibility in meeting the regulatory requirement?					

ECONOMIC IMPACT	Generally, what is this going to cost industry/ affected parties?	
PRA IMPLICATIONS	Would this require additional agency resources (more FTEs)?	
	What are the benefits to public health, industry, and/or the FDA?	
	Can a satisfactory outcome be produced with less costly alternatives?	
PAPERWORK REDUCTION ACT IMPLICATIONS	Would the rule require collections of information (e.g., paperwork, electronic submissions, faxes)? Are they increased or reduced from previous requirements?	
	Would the paperwork requirements impose a significant burden or provide benefits to the Agency?	
COORDINATION W/ OTHER BRANCHES OF FDA	What divisions of CDER would be affected by the proposal? Have they had input into/concurred with the proposal?	
	What other parts of the Agency/Centers would be affected by the proposal? Have they had input into/concurred with the proposal?	

Attachment B – Office of Regulatory Policy Recommendation Form

Office of Regulatory Policy

Date: _____

Suggestions for modifying/improving the proposed rulemaking initiative:

Recommendation for proceeding with proposed rulemaking initiative:

Signature: _____