Appendix 2: Regulation Concept Paper Template

Regulation Concept Paper Template

Instructions: Document should be no more than two pages long.

I. What is the issue?
Enter one or two sentences outlining the issue to be addressed by the rulemaking.

II. What is the priority?
Enter the priority of the rulemaking; e.g., low, medium, or high. Justify your selection in this field.

III. What are the key elements of the proposed action?
Enter one or two paragraphs discussing the key elements of the proposal including any other regulatory options considered and why they were rejected; why you recommend addressing the issue this way, as opposed to taking another action or no action; what resistance we may encounter to the rulemaking (e.g., challenges to legal authority, strong opposition from a particular group); how the rule will be enforced; and any anticipated public response to the rulemaking.

IV. Under what statutory and regulatory authority is the rulemaking being instituted?
Enter one sentence referencing the legal authority for the rulemaking (OCC should be consulted on the agency's legal authority).

V. How does the rulemaking support FDA's mission?
Enter one sentence describing how the rulemaking furthers the agency's (Strategic Action Plan) public health mission.

VI. Who are the principal authors and initiating CBER Office/Division?
Identify the most appropriate person to facilitate the rulemaking (the "Champion" and the CBER Office and Division; and others who might be important for consultation purposes (e.g., information technology expertise, review management expertise, etc.).

VII. What is the projected timeline for publication?
Identify how long you think it will take to develop and implement the rulemaking. Include how long you think it will take to get the rule out of the lead office.

VIII. Is there a mandatory deadline by which the rulemaking must be published?
Yes or no. If yes, provide one sentence explanation.

IX. What components within FDA will the rulemaking affect?

Identify both the CBER and agency components you expect should be included in the rulemaking, as well as those components that may be affected upon its implementation. Identify other agencies you expect should review the rule.

X. Will a guidance or other document (e.g., citizen petition response) accompany the rulemaking?
Yes or no. If yes, provide an explanation.

XI. Does the rulemaking individually or cumulatively have a significant effect on the human environment that would require an Environmental Assessment or Environmental Impact Statement?
See 21 CFR part 25, and 21 CFR § 25.31.
Yes or no.

XII. Are there economic considerations?
Yes or no. If yes, provide an explanation.

Assess whether the regulatory action chosen is the most cost effective in light of other regulatory alternatives. (E.O. 12866).

Assess whether the rulemaking will have a substantial impact on small businesses. (Regulatory Flexibility Act).

Assess whether implementation of the rulemaking by local governments or the private sector would result in aggregated costs exceeding the current threshold ($127 million). (Unfunded Mandates Reform Act).

Are there new paperwork burdens triggered by the rulemaking?
Yes or no. If yes, provide an explanation.

Enter one sentence considering whether *new* paperwork burdens will be triggered by the rulemaking. Approved information collections may be referenced at http://intranet.fda.gov/omp/pra/Approved_ICRs.htm#CBER on the Intranet.

XIII. Anything Else?
Provide any additional pertinent information.

XIV. Approval Signature(s) and Date
Obtain appropriate signature(s) (e.g., Office Director), and date.