SOPP 8014: Procedures for the Preparation, Routing, and Issuance of Regulations

Version #1

Effective Date: October 30, 2008

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1. Purpose

This SOPP serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for the development of CBER regulations. This document provides guidance on the procedures for developing regulations from the concept stage to preparing, routing, and publishing regulations developed by CBER.

2. Definitions

See **Appendix 1** for definitions of terms used in this SOPP.

3. Background and Policy

Under the Federal Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), FDA has authority to publish substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency that are necessary to implement and enforce legislative acts. (5 U.S.C. § 552(a)(1)(D)). The Federal Food, Drug, and Cosmetic Act and the Public Health Service Act also provide FDA with rulemaking authority. CBER regulates biological products under the Public Health Service Act (42 U.S.C. 262 and 264) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Under these authorities, FDA issues implementing regulations that further inform industry and the public how the provisions of Congressional statutes and legislative acts affecting products regulated by CBER will be applied. Rules on FDA's promulgation of regulations for the efficient enforcement of the law are located in 21 CFR 10.40. FDA also issues regulations when the agency determines policy decisions directly affect the public or regulated industry. The rulemaking process set out in section 553 of the APA (5 U.S.C. 553) requires that every regulation, with certain exceptions (e.g., procedural regulations), must publish as a proposal in the Federal Register (FR) for public review and comment before promulgation in final form. FDA ordinarily allows a minimum 75 day comment period during which the public and regulated industry can review the proposal and submit comments to the agency. Comments are received by submission to the Division of Dockets Management (DDM) under the appropriate docket number. When the proposed rule's comment period closes, FDA must analyze all comments to the Docket and prepare a detailed preamble to the final rule stating the nature of each type of comment and FDA's response. Once a final rule is in effect, the regulation is enforceable in the courts. Comment period length for a proposed rule may vary depending on the nature and complexity of the proposal and can be extended, via publication of a notice in the FR, if FDA deems it appropriate. Also, any interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the

DDM stating the grounds for the request (21 CFR 10.40(b)(3)).
The following actions can begin the rulemaking process for CBER-regulated products:

- A CBER Office identifies the need for rulemaking (e.g., new technologies not addressed in existing regulations).

- Enactment of a new law requiring regulations or for which new regulations are needed for smooth implementation.

- Review of industry practices or other events by FDA's Office of the Commissioner (e.g., Office of Policy, Office of Legislative Affairs) or by other FDA Centers with assessment of the need for regulations.

- A request from FDA's Office of the Commissioner. Such a request usually occurs in the context of inter-center rulemaking. Inter-center regulations affect and are drafted by more than one FDA Center. One Center takes the lead for processing the regulation for publication in the FR.

- A request from the public.

4. Steps in Regulation Development

This section provides a brief overview of the **10 major steps** that comprise regulation development and clearance. Although the details of the process may vary given the specifics of a particular rulemaking, this basic framework is used for most of the regulations CBER develops.

The roles, responsibilities, and procedures associated with each of these steps are detailed in the next section of this SOPP.

I. The Concept Paper

When a CBER Office wishes to initiate a rulemaking, the Office fully develops the regulation's core concepts through the development of a Concept Paper. The Concept Paper provides the foundation of the regulation by including the relevant policy decisions and rationales for why a regulation is needed. Generally no more than two pages in length, the Concept Paper identifies the objective(s) of a proposed rulemaking and analyzes all issues relevant to the rulemaking.

A thorough and concise Concept Paper:

- Identifies the **ISSUE(S)** to be addressed, the policy decisions and rationales for why CBER recommends addressing the issue(s) with rulemaking, and any deadlines.
- Discusses a **SUMMARY OF PROPOSED ACTION** outlining the key elements of the proposal, what other options were considered and why they were rejected, any expected obstacles, the legal authority for the rulemaking, and how the proposed action supports the agency's Strategic Action Plan.

- Discusses the **PRELIMINARY COST/BENEFIT ANALYSIS** and **PAPERWORK BURDEN ANALYSIS** including a brief assessment of costs and benefits to industry, FDA, and the impact on small entities.
- Identifies any **STAKEHOLDER INTEREST**, i.e., anticipated reaction from interested parties as well as a description of comments already received, if any.
- Identifies the Champion, other affected Offices, and/or Centers.
- Identifies the target publication date, and any Congressionally mandated deadlines.

Appendix 2 includes a Concept Paper template. Refer to Section 5.I. of this SOPP for the approval process of a Concept Paper.

II. The Work Plan

Once a Concept Paper is approved by the appropriate parties in CBER, CBER's Regulations and Policy Staff (RPS) Project Officer will develop a Work Plan for the regulation. A Work Plan is a step-by-step breakdown that describes management of the regulation's development. A Work Plan serves to clarify the expectations for each participant group in the regulation development process and provides those responsible for the rule's review and clearance with estimated distribution and due dates.

The Work Plan includes the following items, including any other appropriate step(s) given the specific rulemaking:

Actual completion dates for:

- Drafting of the Concept Paper
- Clearance of the Concept Paper at all appropriate level(s)

Target completion dates for:

- Drafting of the Codified Language
- Clearance of the Codified Language at all appropriate level(s)
- Drafting of the Paperwork and Economic Sections
- Drafting of the Preamble
- Clearance of the Preamble at all appropriate level(s)
- Completion of the Full Document
- Final clearance of the regulation at all appropriate level(s) prior to publication

Appendix 3 includes a Work Plan template.

III. The Codified Language

The Codified Language is the section of a rulemaking that has a binding effect and sets out FDA's additions and/or changes to the Code of Federal Regulations (CFR). It is important to remember that regulations are enforceable as law and bind industry and FDA. Although a detailed background of issues pertaining to a regulation is included in its Preamble, this

background information does not publish in the CFR. Accordingly, the regulation published in the CFR must be understandable as a "stand alone" provision.

IV. Codified Language Review Cycle

Once a draft of the Codified Language is complete, the appropriate parties within CBER will review and provide input on the Codified Language. Appropriate parties include the RPS Project Officer, RPS Director, Champion, Lead Office (including the Lead Office Associate Director for Policy (ADP)), other Office ADPs if those Offices will clear the document, all members of the Working Group, if applicable, and all other key players, as appropriate. Depending on the complexity of the regulation, additional review cycles for the Codified Language may be necessary.

V. The Preamble

The Preamble describes the regulation, explains why the regulation is necessary, how it will be implemented, and provides further explanation of the various provisions of the regulation. It also cites the legal authority for the rulemaking.

The Preamble comprises several components, with some distinctions between proposed rules and final rules.

- Agency Caption –The agency caption states that FDA is issuing the rulemaking.
- Action Caption – The action caption identifies the type of rulemaking that FDA is issuing (e.g., Proposed Rule, Interim Final Rule, Direct Final Rule, Final Rule, etc.).
- Summary Paragraph – The summary paragraph identifies what action FDA is taking, why the action is necessary, and the intended effect of the action.
- Dates Caption –The dates caption presents the dates that are essential to the rulemaking (e.g., deadlines for public comment period, the effective date of the rulemaking, etc.).
- Addresses Caption – The addresses caption contains any addresses the public needs to be aware of (e.g., address for the mailing of public comments).
- For Further Information Caption – The further information caption identifies a point person within FDA who is the primary contact for questions about the rulemaking. This point person is usually the RPS Project Officer.
- Supplementary Information for Proposed Rules –The supplementary information for a proposed rule includes: a section on the background and history of the regulation, a discussion of any major issues, a section-by-section highlight of the proposed rule, a request for comments, and all appropriate assessment statements (i.e., Economic, Paperwork Burden, Environmental, Federalism, etc.).
- Supplementary Information for Final Rules – The supplementary information for a final rule includes: all applicable portions of the proposed rule's supplementary information, a section-by-section highlight of the final rule, a summary of the comments received on the proposed rule and FDA's corresponding responses, and all appropriate assessment statements (i.e., Economic, Paperwork Burden, Environmental, Federalism, etc.).

Special Note for Interim and Direct Final Rules: The supplementary information of an interim final rule includes a good cause statement as to why prior notice and comment on the

rulemaking is not warranted (21 CFR 10.40(e)(1)). The supplementary information of a direct final rule includes a justification for why direct final rulemaking is appropriate.

VI. Preamble Review Cycle

Once a draft of the Preamble is complete, the appropriate parties within CBER will review and provide input on the Preamble language. Appropriate parties include the RPS Project Officer, RPS Director, Champion, the Lead Office (including the Lead Office ADP), other Office ADPs if those Offices will clear the document, all members of the Working Group, if applicable, and other key players, as appropriate. Depending on the complexity of the regulation, additional review cycles for the Preamble may be necessary.

VII. CBER Clearance of a Regulation

Once the regulation is fully developed (i.e., all review cycles for the Codified Language and the Preamble are complete and agreed upon versions of the Codified Language and the Preamble are combined into a Full Document), the appropriate CBER Offices and other FDA Centers/Offices will review and comment on the regulation as appropriate.

Appendix 4 provides a sample CBER Clearance Record, used to document the Offices and individuals responsible for review of and comment on the regulation at this stage in development.

VIII. Final Agency Clearance of a Regulation

Once CBER Clearance is complete and there is a revised regulation incorporating all agreed upon comments, the RPS Project Officer circulates the regulation for final clearance across FDA.

Appendix 5 provides a sample Blue Sheet (Final Clearance Record), used to obtain final clearance of the regulation across the Agency.

IX. Publication in the Federal Register

Once the regulation clears FDA, and the Department of Health and Human Services (DHHS) and/or the Office of Management and Budget (OMB), as necessary, the regulation will be forwarded to the Office of the Federal Register (OFR) for publication. The OFR will schedule a publication date.

X. The Administrative Record

The Administrative Record includes information FDA considered or relied on directly or indirectly when making a decision, including the existence of contrary evidence to FDA's position and FDA's handling of contrary evidence. The Administrative Record is often reviewed to understand why a decision was made on the matter. FDA, the Courts, Congress, the Office of the Inspector General, the General Accountability Office, the general public, and the press might review the Administrative Record.

FDA retains the Administrative Record indefinitely. It is not subject to other records retention policies within CBER or FDA. If a regulation's Administrative Record is flawed, the regulation, if challenged, may be invalidated and discovery and testimony may be needed to supplement the record. Therefore, compiling an accurate and thorough Administrative Record is a critical part of developing the regulation.

5. Responsibilities and Procedures for the Major Steps of Regulation Development

I. The Concept Paper

A. The Lead Office, generally:

- Designates a knowledgeable staff person as the Champion, who is responsible for developing the Concept Paper.
- Establishes a Working Group of key individuals, as appropriate, to assist in developing the rulemaking concepts and implementation strategy.
- Identifies other affected CBER Offices and FDA Centers.
- Conducts an analysis of all issues relevant to the rulemaking.
- Identifies any issues that need to be resolved before the process can proceed further, and the decision-making authority needed to resolve those issues.
- Identifies the individuals who will ultimately sign-off on the regulation and ensures that their comments are solicited during development of the Concept Paper.
- Works with the Center's Policy Coordinating Committee to identify which CBER Offices and FDA Centers need to review and approve the Concept Paper, and which Offices should receive an "FYI" copy, with an option to comment.

A.1. The Champion:

- Solicits comments from any individual within the agency who is knowledgeable on the subject or who may have relevant information.
- Develops the Concept Paper for approval by the Lead Office Director.

A.2. The Lead Office Director:

- Reviews and clears the Concept Paper after completion by the Champion.
- Submits the Concept Paper to the RPS Director and to the CBER Associate Director for Policy (ADP) for approval.

B. RPS Director:

- Circulates the Concept Paper to the identified CBER Offices/FDA Centers.
- Provides recommendations on the Concept Paper to the CBER ADP.

CBER ADP

- Approves the Concept Paper, so the rulemaking can go forward.
- Consults with other CBER/FDA parties for their input on the Concept Paper, as appropriate.

II. The Work Plan

A. The RPS Project Officer (assigned by the RPS Director):

- Drafts the Work Plan after the Concept Paper is cleared at all appropriate level(s).
- In developing the Work Plan, the RPS Project Officer:
    - Reviews the scope and specifics of the regulation to ensure their understanding of the end product and a timeframe for completion.
    - Identifies all tasks needed for publication of the regulation in the FR.
    - Identifies the key player(s), both individual(s) and Office(s), that must provide approval and clearance at each step.
    - Estimates a **reasonable** timeframe for completion of each task.
    - Obtains agreement on the Work Plan from the key players.
    - Shares a copy of the Work Plan with the key players.
    - Sets reasonable timeframes allowing for timely and sufficient completion of each step. Often, the Lead Office provides the RPS Project Officer with suggested timeframes for the project.
    - Updates and reports any deviations from the Work Plan to the RPS Director and/or the RPS Team Leader. The RPS Project Officer should also update the Lead Office ADP (if overseeing the Champion), the Champion, and/or the Working Group, as applicable.
    - For those projects experiencing delays, promptly discusses with the RPS Director the need for a meeting to address delays and sets up such meeting if needed.

III. The Codified Language

A. The RPS Project Officer, Champion, and/or Working Group (if applicable):

- Work together to draft the regulation's Codified Language. In doing so they:
    - Review the Concept Paper – The Concept Paper is a good resource for drafting the Codified Language. Prior to drafting the Codified Language, the regulation writer(s) must read the Concept Paper and identify the objective(s) of the rulemaking.
    - Organize the Rule – Organization of a rule's subject matter and its location in the CFR facilitates the writing process. The RPS Project Officer and/or Champion determine what parts and sections of the CFR are affected by the rulemaking and propose a CFR citation for the rule.
    - Adhere to the Standard Format of Regulations – The standard format of proposed rules and final rules are set out in the OFR's Document Drafting Handbook (DDH). The DDH provides guidance to regulation writers on drafting regulations that comply with OFR's publication requirements. In accordance with the DDH, regulation writers must use the correct amendatory language when drafting proposed and final rules.
    - Use Plain Language (also known as Plain English) – Regulation writers must write all regulations in "Plain English." Clarity of a regulation's text is linked to greater compliance with a regulation. The DDH contains a detailed discussion of "Plain English" in the section entitled "Making Regulations Readable."

IV. Codified Language Review Cycle

A. The RPS Project Officer:

- Circulates the draft of the Codified Language for comment to: the Champion, the Lead Office (including the Lead Office ADP), other Office ADPs if those Offices will clear the document, all members of the Working Group, and other key players, as appropriate. Depending on the complexity of the regulation, more than one review cycle for the Codified Language may be necessary.
- Consolidates comments on the draft Codified Language and disseminates consolidated comments to the Champion, Lead Office (including the Lead Office ADP), and the Working Group, if applicable, as well as all other appropriate key players.
- Schedules meetings, as needed, to resolve comments on the draft Codified Language.
- Revises the draft Codified Language consistent with agreed upon comments.

B. The Lead Office, including the Champion and ADP:

- Reviews Codified Language and provides RPS Project Officer with comments by the specified date.

C. Other Office ADPs:

- Review Codified Language and provide RPS Project Officer with comments by the specified date.

D. Working Group:

- Reviews Codified Language and provides RPS Project Officer with comments by the specified date.

V. The Preamble

A. The RPS Project Officer, Champion, and/or Working Group (if applicable):

- Work together to draft the regulation's general Preamble language.

B. The RPS Project Officer:

- Determines whether the regulation has any paperwork burden, economic, environmental, and federalism implications that FDA must further discuss.

For Paperwork Burden:

- The RPS Project Officer prepares a paperwork assessment statement for the regulation in accordance with the Paperwork Reduction Act of 1995 (PRA).
- Prior to drafting the assessment statement, the RPS Project Officer contacts the liaisons in the Paperwork Reduction and Records Management Staff (PRA Staff) within the Office of the Chief Information Officer, Office of the Commissioner, for specific discussions of

a given regulation's paperwork burden. The RPS Project Officer involves the Champion and other staff, as appropriate, in these discussions.

- If it is determined that the regulation does not have paperwork burden or that any paperwork burden is covered by current Office of Management and Budget (OMB) packages, the RPS Project Officer includes boiler plate language in the regulation stating that the rule contains no collections of information or includes information on the relevant OMB packages.
- Any comments received on the paperwork burden of a proposed rule are addressed in the "Paperwork Reduction Act of 1995" section of the final rule.

For Economic Assessment:

- The RPS Project Officer coordinates development of an economic assessment statement as necessary under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act.
- Assistance in preparing economic threshold assessments is available from the Economics Staff within the Office of Planning, Office of the Commissioner.
- In general, if FDA determines that the regulation does not have a significant economic impact, the RPS Project Officer includes boiler plate language in the regulation stating that an economic assessment statement is not needed. However, in certain circumstances, the Economics Staff may need to include a more detailed response.
- Any comments received on the economic implications of a proposed rule are addressed in the "Analysis of Impacts" section of the final rule.

For Environmental Impact and Federalism

- The RPS Project Officer completes the environmental and federalism sections of the Preamble. Template language is normally used for these sections, but further consultation within FDA would be necessary if there is any significant impact on these factors.

C. PRA Staff in the Office of the Chief Information Officer, Office of the Commissioner

- Available to consult with the RPS Project Officer and other parties interested in the paperwork burden of a regulation.

D. Economics Staff in the Office of Planning, Office of the Commissioner

- Available to consult with the RPS Project Officer and other parties interested in the economic implications of a regulation.

VI. Preamble Review Cycle

A. The RPS Project Officer:

- Circulates the draft of the Preamble for comment to: the Champion, the Lead Office (including the Lead Office ADP), other Office ADPs if those Offices will clear the final document, all members of the Working Group, and other key players, as appropriate.

Depending on the complexity of the regulation, more than one review cycle for the Preamble may be necessary.

- Consolidates comments on the draft Preamble and disseminates consolidated comments to the Champion, Lead Office (including the Lead Office ADP), and the Working Group, if applicable, as well as all other appropriate key players.
- Schedules meetings, as needed, to resolve comments on the draft Preamble.
- Revises draft Preamble consistent with agreed upon comments.

B. The Lead Office, including the Champion and ADP:

- Review Preamble Language and provide RPS Project Officer with comments by the specified date.

C. Other Office ADPs:

- Review Preamble Language and provide RPS Project Officer with comments by the specified date.

D. Working Group:

- Reviews Preamble Language and provides RPS Project Officer with comments by the specified date.

VII. CBER Clearance of a Regulation

A. The RPS Project Officer:

- Sends the regulation, and accompanying CBER Clearance Record to the following in sequential order:
    - RPS Team Leader (2 weeks standard review)
    - RPS Director (2 weeks standard review)
    - CBER Offices and FDA Centers/Offices, as applicable – The RPS Project Officer requests review and comments from the Offices by a specific date, typically within two to four weeks (depending on the size of the rule).
    - CBER ADP – The RPS Project Officer consolidates all of the comments received from the individual Offices/Centers and sends these comments to the Champion and to the CBER ADP for review within two to four weeks.
- Provides the Champion the consolidated comments received from the CBER Offices, FDA Center(s), and the CBER ADP.
- If needed, the RPS Project Officer may schedule meetings with the appropriate parties to discuss comments.
- The RPS Project Officer incorporates agreed upon comments and revisions and produces a revised regulation.

B. The Champion:

- The Champion consults with other appropriate staff in the Lead Office in considering all comments submitted by other CBER Offices, FDA Center(s) (if applicable), and the CBER ADP.

VIII. Final Agency Clearance of a Regulation

A. The RPS Project Officer:

Within CBER, the RPS Project Officer sends the regulation, and accompanying Blue Sheet, to the following, in sequential order:

- RPS Team Leader
- RPS Director
- CBER Lead Office and other CBER Offices (as appropriate)
- CBER Associate Director for Policy
- CBER Center Director
- Other FDA Centers/Offices affected by the regulation. The RPS Project Officer may request clearance from other FDA Centers/Offices concurrent with CBER Director clearance.

Once CBER clears the regulation, the RPS Project Officer sends the regulation and accompanying Blue Sheet to the following, in sequential order:

- PRA Staff
- Economics Staff
- Office of Chief Counsel (OCC)
- Office of Policy: Regulations Policy Management Staff (RPMS) and Regulations Editorial Staff (RES)

B. Office of Chief Counsel (OCC)

If OCC makes any changes to the regulation during its sign-off, OCC sends the document back to RPS. Once the RPS Project Officer makes OCC's requested changes and receives OCC final signoff, the regulation proceeds to the next level of clearance. If OCC's sign-off results in significant changes to the regulation, it may be necessary to re-circulate the document through CBER, on a limited basis.

C. Office of Policy

Within the Office of Policy, the Regulations Policy Management Staff (RPMS) and the Regulations Editorial Staff (RES), facilitate the regulation's final review and publication.

C.1. RPMS and RES

- RPMS reviews the regulation for conformance with FDA policies and gives the document to RES for preparation in the FR format.
- RES edits the document in accordance with the FR format. If RES makes substantive changes to the document, RES contacts the RPS Project Officer to discuss these changes.

Depending on the nature of the changes, a new round of clearance of the document within CBER and OCC may be required. After fully editing the document, RES returns the regulation to RPMS. The RPS Project Officer should request that RPMS provide a copy of RES' editorial changes.

- Once RPMS receives the formatted document from RES, RPMS forwards the document to the appropriate official for signature. Typically, the Assistant Commissioner for Policy signs the document but depending on the regulation's significance, the Commissioner or the Secretary for the Department of Health and Human Services (DHHS) may sign the regulation.
- RPMS coordinates the review of regulations by DHHS and OMB. RPMS sends the regulation to DHHS before OMB. Each quarter (calendar year), RPMS requests that RPS provide an OMB Write-up and Work Plan for any regulation that is expected to clear FDA by the specified time period. The RPS Project Officer is responsible for drafting the OMB Write-up and Work Plan. The OMB Write-up and Work Plan are needed for most rulemakings and are used by FDA, DHHS, and OMB to determine the significance of a document and the necessity of DHHS and OMB review and sign-off. The RPS Team Leader and/or Director should review the OMB Write-up and Work Plan before it is forwarded to RPMS by the RPS Team Leader.

Appendix 6[1] contains the OMB Write-up template and instructions on how to complete the template. Refer to the "Steps in Regulation Development" section of this SOPP for information on how to draft a Work Plan (Appendix 3).

D. DHHS and OMB

- If DHHS determines that a regulation is significant or not significant but review is warranted, DHHS conducts a review of the regulation. There is no established deadline by which DHHS must complete its review.
- If OMB determines that a regulation is significant, OMB has a 90 day formal review period to conduct its review and may request a 30 day extension.
- Once DHHS and OMB reviews are complete, their comments are forwarded to RPS by RPMS. The RPS Project Officer works with the Champion, the Lead Office, and others as appropriate (e.g., Economics Staff), to address DHHS and OMB comments. The RPS Director and/or Team Leader reviews the responses and consults with the CBER ADP and OCC as appropriate.
- DHHS requests that FDA submit responses to all DHHS comments at the same time. For those comments that FDA accepts, track changes on the document are acceptable. For those DHHS comments that FDA does not accept or where further explanation is needed, FDA submits a memorandum to DHHS outlining its responses.

IX. Publication in the Federal Register

A. RPMS

- Forwards the regulation to the OFR for publication once the regulation has cleared all levels, including DHHS and OMB, if applicable.

B. OFR

- Schedules an FR publication date for the regulation.

C. RPS

- Sends an email informing the CBER Director, CBER ADP, Office ADPs, and other relevant parties, of the scheduled publication date.

C.1. The RPS Project Officer

- Prepares the rulemaking's reference package. Any references that are included in a rulemaking must be submitted to the Division of Dockets Management (DDM) prior to display and publication of the rule (21 CFR 10.40). The RPS Project Officer is responsible for requesting the references from the Lead Office, preparing the reference package, and submitting this package to DDM, before the regulation goes on display at the OFR.

X. Compiling the Administrative Record

A. The RPS Project Officer:

- Must continually compile the substantive information that FDA considered or relied on when developing the rulemaking. This information makes up the rulemaking's Administrative Record (21 CFR 10.3(a)).
- Completes a rulemaking's Administrative Record generally within 2 months of the rule's publication in the FR. Depending on the complexity of the rulemaking, this timeframe may vary.
- Discusses and obtains approval from, the RPS Director for any Administrative Record the RPS Project Officer believes cannot be compiled within 2 months. In these cases, the RPS Director should identify an estimated timeframe by which the Administrative Record should be compiled.

B. RPS Director:

Identifies an appropriate time for completion of a rulemaking's Administrative Record when the RPS Project Officer believes it cannot be compiled within 2 months.

5. References

Administrative Procedure Act (APA)
Public Health Service Act (PHS)
Federal Food, Drug, and Cosmetic Act (FD&C)

- Document Drafting Handbook
- http://www.archives.gov/federal-register/write/handbook

6. Effective Date

This SOPP is effective upon posting on the CBER internet.

7. History

Comment/ Revision	Approved By	Approval Date	Version Number	Comment
RPS/ADP	Robert A. Yetter, PhD	Oct 29, 2008	1	Original

8. Appendices

- Definitions (PDF - 18KB) [Appendix 1]
- Regulation Concept Paper Template (PDF - 25KB) [Appendix 2]
- Work Plan Template (PDF - 22KB) [Appendix 3]
- CBER Clearance Record (PDF - 29KB) [Appendix 4]
- Blue Sheet (Final Clearance) Record (PDF - 49KB) [Appendix 5]
- OMB Write-up Instructions and Template (PDF - 153KB) [Appendix 6]