Appendix 1: Definitions

Champion: Member of the initiating (Lead) CBER Office that is the primary Office contact for a regulation in development.

Code of Federal Regulations (CFR): The codification of the general and permanent rules published in the FR by the executive departments and agencies of the Federal Government.

Codified Language: The section of a rulemaking that has a binding effect and sets out FDA's additions and/or changes to the CFR.

Direct Final Rule (DFR): A final rule issued without a notice of proposed rulemaking (NPRM) that is to take effect without further action at a specified future date unless someone submits a substantive adverse comment to the rule. When FDA issues a DFR, the agency simultaneously issues a proposed rule in the event that a substantive adverse comment is submitted. If a substantive adverse comment is submitted, FDA will revert to a NPRM. FDA issues a direct final rule when the action covered by the rule is non-controversial and is not likely to elicit adverse comments. If no substantive adverse comment is received, FDA issues a notice in the FR noting the date on which the DFR goes into effect.

Federal Register (FR): Published by the Office of the Federal Register (OFR), the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as Executive Orders and other presidential documents.

Final Rule: The regulation finalized for implementation, published in the FR (preamble and codified), and codified in the CFR.

Interim Final Rule (IFR): A final rule that takes effect immediately or on short notice without a NPRM but on which FDA invites comments and may change the rule based on the comments received. An interim final rule is usually followed by a final rule which may include revisions made as a result of FDA's consideration of the comments.

Preamble: Analysis preceding a proposed or final rule that clarifies the intention of the rulemaking and any ambiguities regarding the rule. Responses to comments made on a proposed rule are published in the preamble preceding the final rule. Preambles are published only in the FR and do not have a binding effect.

Proposed Rule/Notice of Proposed Rulemaking (NPRM): An agency process, subject to public notice and comment, for formulating, amending, or withdrawing a regulation. A proposed rule provides FDA's suggested regulatory changes to the CFR. It also provides the public with notice of and an opportunity to comment on the regulatory changes being undertaken by the agency.

Regulation (21 CFR 10.3(a)): An agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with 21 CFR 10.90(a), each agency regulation will be published in the Federal Register and codified in the Code of Federal Regulations.

Rule: The terms "rule" and "regulation" are interchangeable for the purposes of this SOPP.

Rulemaking: The process used by CBER to formulate, amend, or withdraw a rule or regulation.

RPS: An acronym for CBER's Regulations and Policy Staff.

RPS Project Officer: Member of RPS assigned to a certain project with primary responsibility for coordination of the regulation development process for that project.