SOPP 8412: Review of Product Labeling

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Table of Contents

I. Purpose 1
II. Scope 1
III. Background 2
IV. Definitions 2
V. Policy 3
VI. Responsibilities 5
VII. Procedures 6
VIII. Appendix 11
IX. References 11
X. History 14

I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for the review of labeling for human drug and biologic products, including combination products.

II. Scope

A. This SOPP applies to the review of product labeling for drugs and biological products regulated under Biologics License Applications (BLA), New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), and their respective supplements.

B. This SOPP applies to the review of patient-oriented labeling that is submitted with human factors (HF) study protocols for combination products.

C. This SOPP does not apply to labeling submitted in annual reports. Refer to *SOPP 8411.1*: *Administrative Handling and Review of Annual Reports for Approved Biologics License Applications (BLAs)* for procedures to be followed for labeling submitted in annual reports.

D. This SOPP does not apply to medical devices, including In Vitro Diagnostics (IVDs) regulated under the BLA pathway, refer to *JA 910.04: Labeling Review of Licensed In Vitro Diagnostic Products.*

E. This SOPP does not apply to human blood and blood components. For labeling reviews associated with human blood and blood components, refer to *JA 910.05: Labeling Review of Whole Blood and Blood Components including Source Plasma and Source Leukocytes.*

III. Background

A. Proper labeling of approved products is a requirement of the Food, Drug, and Cosmetic (FD&C) Act and the Public Health Service (PHS) Act. Labeling is reviewed as part of a BLA, NDA, ANDA, and their respective supplements, annual reports, or as product correspondence, when appropriate, to ensure the information is correct and that the product is not misbranded. The general labeling provisions are found in the Code of Federal Regulations (CFR) at 21 CFR Part 201.

B. CBER relies on labeling reviews to ensure accurate information is provided in a manner that physicians and patients can understand for all age groups for whom the product is intended. These reviews include the content of labeling (i.e., prescribing information (PI), Medication Guide (MedGuide), Patient Package Insert (PPI)), Patient Oriented Labeling (POL), Instructions for Use), the proper (established) name, the proprietary (trade or brand) name, and the content and format of package and container labels.

C. The mechanism for reporting changes to labeling varies according to the type of change and the change's potential for having an adverse effect on product identity, strength, quality, purity, or potency as described in 21 CFR 601.12, 314.70, and 314.97. The reporting categories allowed by these regulations include several different administrative processes for labeling submission and review. For drugs and biologics subject to 21 CFR 314.70, 314.97, and 601.12, respectively, changes to a product package label, container label, package insert, Medication Guide and directions for use require either: (1) submission of a supplement with FDA approval needed prior to product distribution (Prior Approval Supplement (PAS)); (2) submission of a supplement with Changes Being Effected (CBE); or (3) submission of the final printed labeling in an annual report.

IV. Definitions

A. Content of labeling – All text, tables, and figures, such as contents of the package insert (or professional labeling), patient package insert, and medication guide(s) required under 21 CFR 201.100(d)(3). **Note:** The Physicians Labeling Rule (PLR) and the Pregnancy Labeling and Lactation Rule (PLLR) specify the format for the content of labeling.

B. First Use Notification – A submission to FDA that includes the final printed labeling and final content of labeling used when an approved product was initially distributed or sold.

C. Label – Display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity (21 CFR 1.3(b)).

D. Labeling – All written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce (21 CFR 1.3(a)). **Note:** Labeling includes the container labels, package insert (also referred to as professional labeling), the patient package insert, medication guides, instructions for use, risk management materials, and promotional labeling.

E. Patient-oriented labeling – Patient instructional materials that include only Instructions for Use (IFU) and Quick Reference Guides (QRGs).

F. Product Identifier – A standardized graphic that includes the standardized numerical identifier, lot number, and expiration date of the product, in both human-readable and machine-readable formats (see section 581(14) of the FD&C Act).

G. Standardized numerical identifier – A set of numbers or characters used to uniquely identify each package or homogenous case, composed of the National Drug Code (NDC) combined with a unique alphanumeric serial number of up to 20 characters (see section 581(20) of the FD&C Act).

H. Structured Product Labeling (SPL) – The required electronic format for submitting the content of labeling. SPL utilizes Extensible Markup Language (XML).

V. Policy

A. SPL formatted content of labeling (.XML file), the current standard for electronic content of labeling submissions, is to be submitted with original BLA/NDA/ANDA submissions, efficacy supplements, and all supplements that require review of labeling. Refer to the *Guidance for Industry: Providing Regulatory Submission in Electronic Format - Content of Labeling*. It is recommended that applicants submit the annotated Microsoft (MS) Word-formatted version (.docx file) of the Content of Labeling.

B. Labeling negotiations for original and supplemental BLA/NDA/ANDA submissions are performed using the track changes (redline/strikeout) function in MS Word. **Note:** there may be instances that require explanatory text or separate annotation within the document or as a separate document.

C. Labeling revision requests will be as complete as possible when sent to the applicant. The applicant is responsible for revising and resubmitting proposed labeling for review.

D. A revised SPL is not required during labeling negotiations.

E. Under section 582(a)(8) of the FD&C Act, changes made to the drug package label solely to incorporate the product identifier may be submitted in an applicant's annual report in accordance with 21 CFR 314.70(d) (or any successor regulation).

F. CBER requests a different NDC package code for each nested package level.

G. During the review of an original BLA, NDA, or ANDA, CBER assigns a descriptive Proper (Established) name. CBER may use certain nomenclature conventions (e.g., United States Adopted Names (USAN), International Nonproprietary Naming (INN)). An applicant may propose a proper name in their submission for CBER to evaluate, but CBER will assign the proper name.

H. At the time of first use (i.e., at time of distribution or sale), the applicant must submit the final content of labeling and the final printed labeling as product correspondence or in an annual report if its submission coincides with distribution. This is called the First Use Notification.

1. Final content of labeling is to be submitted in SPL format.

2. Final printed labeling may include electronic rendering/images (e.g., .jpeg) of the packages and containers.

I. Advertising and promotional labeling must be submitted to FDA on Form FDA 2253 (see 21 CFR 601.12(f)(4) and 314.81(b)(3)(i)).

J. Under the accelerated approval pathway (see 21 CFR 601.45):

1. Promotional materials that will be disseminated within 120 days of approval must be pre-submitted and reviewed prior to the BLA's approval.

2. Any promotional materials intended to be disseminated more than 120 days after approval must be submitted at least 30 days before the intended time of initial dissemination.

K. For multiple supplements that include labeling revisions under review for the same product/same applicant, a coordinated review of all submitted label changes should be conducted.

1. Upon receipt of approved language from a CBER review committee, the newly approved language will be reviewed by other affected review committees to determine whether that language will impact their review.

2. Labeling coordination is led by a Regulatory Project Manager (RPM).

L. Any approval to revised content of labeling must be reflected in all other open submissions (i.e., applicants of open labeling supplements need to update the proposed labeling in an amendment).

M. Additional labeling supplements should not be submitted while another pending labeling supplement with safety changes is under review. The RPM should make review committees for the same product/same applicant aware of pending safety information for consideration in their on-going reviews.

VI. Responsibilities

A. Review Committee

1. Participates in the labeling review to ensure the content and formatting of the label comply with requirements per applicable regulations.

2. Provides comments as appropriate in review memorandum.

3. Uploads review memorandum to the administrative file and characterizes the review in the regulatory system.

4. Participates in discussions with the applicant regarding label as applicable. If the RPM is not included in the discussion, documents the discussion in the appropriate regulatory system, and alerts the RPM and the chair.

B. Regulatory Project Manager (RPM)

1. Coordinates labeling review activities, such as ensuring assignment of appropriate discipline committee members, scheduling labeling meetings, communicating labeling revision requests to the applicant, etc.

2. Serves as the primary point of contact with the applicant and is recommended to be included in all communications with the applicant.

3. Ensures accuracy of regulatory product information and compliance with content requirements (e.g., National Drug Code (NDC), linear and 2-Dimensional barcodes) for the package and container label(s).

4. Coordinates labeling review across multiple pending supplements that include labeling revisions to ensure labeling includes all recently approved labeling revisions, as applicable.

C. Clinical Reviewer

1. Ensures accuracy of clinically relevant product information in the labeling and compliance with content requirements, i.e., PREA, PLR, PLLR, and all

applicable labeling regulations (see comprehensive list in the references section).

2. Leads content of labeling review discussions.

D. Statistician

Evaluates the accuracy of statistical analysis plans, clinical study reports, analysis data, programs, and data definition as well as the clinical overview and the integrated clinical summaries for efficacy and safety included in the prescribing information relative to the information provided in the submission.

E. Clinical Pharmacology Reviewer

Ensures accuracy of mechanism of action statements, pharmacodynamics, pharmacokinetics, and information on the impact of age, sex, and race in the labeling.

F. Non-Clinical Toxicologist Reviewer

Ensures accuracy of non-clinical toxicology product information relative to information provided in the labeling.

G. Chemistry Manufacturing and Control (CMC) Reviewer

1. Ensures accuracy of chemistry and manufacturing product information provided in the labeling (storage conditions, suitable expiry periods established, etc.).

2. Reviews UNII (Unique Ingredient Identifier) Code request, in collaboration with FDA's Global Substance Registration System (GSRS). See Regulatory Job Aid *JA 900.01: Unique Ingredient Identifier (UNII) Code* for additional information.

3. Ensures that the Drug Listing Data Elements section of the SPL file is correct.

H. Advertising and Promotional Labeling Branch (APLB) Reviewer

1. Performs Proprietary Name Review (PNR).

2. Provides consult to the clinical reviewer and/or chair on the content of the prescribing information labeling from a comprehension and readability perspective.

3. Ensures the information in the labeling is not false or misleading to the target audience(s) (i.e., healthcare providers, patients, special populations) and is in compliance with required labeling regulations.

VII. Procedures

A. General Information

1. For labeling reviews associated with the Pregnancy and Lactation Labeling Rule (PLLR) refer to *JA 910.14: Labeling Review - Pregnancy, Lactation, and Females and Males of Reproductive Potential.*

2. For labeling reviews associated with the consolidation of two applications under one STN refer to *SOPP 8401.8: Procedures for Consolidating Two STNs (Original Applications of BLAs/NDAs) for the Same Product from the Same Applicant.*

3. For information regarding labeling changes related to the issuance or reissuance of Biological Products Licenses refer to *SOPP 8403: Issuance, Reissuance and Voluntary Revocation of Biological Product Licenses.*

4. For labeling reviews associated with the pediatric population, refer to *Guidance for Industry: Pediatric Information Incorporated into Human Prescription Drug and Biological Product Labeling.*

5. For labeling review associated with FDAAA Section 901 for Safety Labeling Changes, refer to *SOPP 8419: Section 505(o)(4) Required Safety Labeling Changes (SLCs)*.

6. For labeling review associated with FDAAA Section 501 for the Pediatric Research Equity Act (PREA), refer to *SOPP 8421: Complying with Requirements under the Pediatric Research Equity Act (PREA)*.

B. Original BLA/NDA/ANDA and Efficacy Supplements

1. Initial processing [refer to *SOPP 8401: Administrative Processing of Biologics License Applications (BLAs) and New Drug Applications (NDAs*) and *SOPP 8401.2: Administrative Processing of BLA and NDA Supplements*]:

   a. Verify labeling (i.e., content of prescribing information, package, and container labels) has been submitted, including an SPL (.XML) file and a MS Word (.docx) version, if applicable**. [RPM]**

   b. Ensure reviewer assignments that cover the types of labeling included in the submission have been made. **[RPM] Note:** A clinical reviewer and an APLB reviewer are assigned to all submissions containing labeling.

2. Examine all labeling components and note any missing information at the Filing Meeting by documenting in the respective discipline Filing Checklist. **[Review Committee Members]**

3. Determine the planned target date for communication or feedback regarding labeling to the applicant and include the date in the Filing Letter. **[Review Committee Members]**

4. Confirm submission of proper name, review, and assign proper name. Refer to *SOPP 8426: Assignment of Biological and Drug Product Proper Names and Biological Suffixes*. **[RPM/Chair] Note:** This is only applicable to original applications.

    a. Identify proper name in user fee cover sheet and request confirmation from RPM. **[RIB]**

    b. Confirm acceptability of proper name. **[RPM/Chair]**

    c. Notify RIB of acceptability. **[RPM]**

    d. Record the proposed proper name in the appropriate regulatory system. **[RIB]**

5. Ensure suffix assignment, if applicable, is processed in accordance with *SOPP 8426: Assignment of Biological and Drug Product Proper Names and Biological Suffixes* and *Guidance for Industry: Nonproprietary Naming of Biological Products.* **[APLB Reviewer, RPM]**

6. If the submission contains a Proprietary Name Review (PNR) request, refer to *SOPP 8001.4: Review of Proprietary Names for CBER Regulated Products* and *JA 910.02: Proprietary Name Review Processing.* **[RPM, APLB Reviewer, Clinical reviewer, chair]**

7. Complete a thorough review of the labeling before the labeling meeting. Ensure compliance with labeling requirements as described in 21 CFR Parts 201, 202, 606, 610, 640, and 660, as applicable. **[Review Committee Members]**

8. Ensure Unique Ingredient Identifier (UNII) Code request is processed in accordance with *JA 900.01: Unique Ingredient Identifier (UNII) Code*. **[RPM, CMC reviewer]**

9. Review labeling from a promotional, comprehension, and readability perspective, including consideration of potential medication errors due to content and format issues. **[APLB Reviewer]**

10. Ensure compliance with promotional labeling and advertising requirements as described in 21 CFR Part 202, *Prescription Drug Advertising*. **[APLB Reviewer]**

11. Ensure accuracy of NDC and bar code information. Refer to *JA 900.08 Review of Package and Container Labels*. **[RPM]**

12. Hold labeling meeting(s) after mid-cycle to discuss proposed labeling revisions. **[Review Committee]**

a. Collaboratively work to identify labeling revisions. **[Review Committee Members]**

b. Summarize labeling issues identified at this meeting for inclusion in the Summary Basis of Regulatory Action (SBRA), as appropriate. **[Committee Chair, RPM]**

13. Send labeling revision(s) to the applicant. Communications may include any revision requests previously communicated but not already addressed (e.g., Filing Letter, Information requests (IRs)s). **[RPM]**

a. This communication may occur anytime during the review; however, it most commonly occurs after the labeling meeting.

b. If needed, labeling meeting(s) may be held with the applicant to resolve labeling disagreements or provide clarification. **[Review Committee]**

14. Upon receipt of draft labeling revised because of labeling negotiations, confirm changes are consistent with requested changes. **[Review Committee, RPM]**

15. Document in the review memorandum any labeling issues that should be identified in the SBRA. **[Review Committee Members]**

16. Notify applicant of acceptance of proposed draft labeling. Request applicant to submit an amendment to the application that contains the final draft labeling. **[RPM]**

a. If approval is imminent with insufficient time to submit a formal amendment:

i. Request the applicant to provide agreed upon labeling via email or fax with agreement to submit labeling in a formal amendment within 2 weeks.

ii. Advise applicant to provide assurance that labeling submitted in the amendment is identical to labeling provided via email/fax.

iii. Document as a telecon in the appropriate regulatory system and upload it into the administrative file.

17. Ensure the approved final draft labeling is included in the Action Package for Posting. Refer to *SOPP 8401.7: Action Package for Posting.* **[RPM]**

C. Labeling Changes Submitted After Approval of Original BLA/NDA/ANDA (21 CFR 314.70, 314.97, and 601.12)

1. Determine if the proposed labeling change is classified under the correct change category (e.g., PAS, CBE, annual report). Verify the manufacturer's name is correct/has not changed. **[Review Committee Members]**

    a. Promptly notify the applicant by telephone and letter, if the category is incorrect, and inform them of the correct category. **[RPM]**

    b. Notify DMPQ if applicant name change is identified. **[RPM]**

2. Request reviewer assignments, as applicable, for clinical, statistics, clinical pharmacology, toxicology, CMC, and APLB. **[RPM] Note:** A clinical reviewer and an APLB reviewer are included on all submissions containing labeling.

3. Provide the submission link to the review committee along with a list of associated submissions with labeling that are actively being reviewed. **[RPM]**

    a. Notify the review committee if there is pending safety information under review for the same product/same applicant. **[RPM]**

    b. Notify the review committee(s) of any pending supplements for the same product/applicant so that the newly approved version of the labeling can be requested from the applicant if the applicant does not proactively amend the submission to include the newly approved labeling. **[RPM]**

4. Ensure the submission includes an SPL that reflects currently approved labeling in addition to the requested change for that submission. **[RPM]**

    a. Perform a comparison to the previous version of changes to approved labeling received and document any differences **[RPM]**

    b. Research open submissions that have labeling changes associated with them to ensure coordination with all open submissions. Refer to *JA 910.03: RMS-BLA Database Search for Labeling Submissions* for information regarding how to find additional/companion submissions containing labeling. **[RPM]**

5. Ensure UNII Code request is processed in accordance with *JA 900.01: Unique Ingredient Identifier (UNII) Code*. **[RPM, CMC reviewer]**

6. Ensure compliance with labeling requirements as described in 21 CFR Parts 201, 202, 606, 610, 640 and 660, as applicable. **[Review Committee Members]**

7. Review labeling from a promotional, comprehension and readability perspective, including consideration of potential medication errors due to content and format issues, as applicable, for example if there are changes to how used or patient use information. **[APLB Reviewer]**

8. Ensure accuracy of NDC and bar code information. Refer to *JA 900.08: Review of Package and Container Labels*. **[RPM]**

9. Communicate labeling revisions to the applicant. Communications may include any revision requests previously communicated but not already addressed. **[RPM]**

    a. This communication may occur anytime during the review.

    b. If needed, labeling meeting(s) may be held with the applicant to resolve labeling disagreements or provide clarification. **[Review Committee Members]**

    c. Ensure communications are correctly characterized and uploaded to the administrative file. **[RPM]**

10. Upon receipt of draft labeling revised because of labeling negotiations, confirm changes are consistent with requested changes. **[RPM]**

11. Notify applicant of acceptance of proposed draft labeling. Request applicant to submit an amendment to the supplement that contains the final draft labeling. **[RPM]**

    a. If approval is imminent with insufficient time to submit a formal amendment:

        i. Request that the applicant provide agreed upon labeling via email or fax with agreement to submit labeling in a formal amendment within 2 weeks.

        ii. Advise applicant to provide assurance that labeling submitted in the amendment is identical to labeling provided via email/fax.

        iii. Ensure the communication is correctly characterized and uploaded into the correct administrative file.

VIII. Appendix

A. Not Applicable

IX. References

A. References below are CBER Internal:

1. CBER Regulatory Job Aids:

    a. JA 900.01: Unique Ingredient Identifier (UNII)

b. JA 900.08: Review of Package and Container Labels

c. JA 910.02: Proprietary Name Review (PNR) Processing

d. JA 910.03: RMS-BLA Database Search for Labeling Submissions

e. JA 910.04: Labeling Review of Licensed In Vitro Diagnostic Products

f. JA 910.05: Labeling Review of Whole Blood and Blood Components including Source Plasma and Source Leukocytes

g. JA 910.14: Labeling Review - Pregnancy, Lactation, and Females and Males of Reproductive Potential

2. SOPPs

a. SOPP 8401.8: Procedures for Consolidating Two STNs (original applications of BLAs/NDAs) for the Same Product from the Same Applicant.

B. References below can be found on the Internet:

1. Relevant Labeling Regulations per 21 CFR

a. Parts §201, §201.10(c), §201.56, §201.57, §201.80, §201.100(d)(3), §202.1, §299.4;

b. Parts §314.50(l)(1)(i), §314.70, §314.81 (b), §314.94(a)(8);

c. Parts §601.12, §601.14(b), §610, §606,122, §640.84, § 640.94 and §660.28.

2. Regulatory Submissions in Electronic Format for CBER-Regulated Products

3. Legislation:

a. Food and Drug Administration Amendments Act (FDAAA), September 2007

b. Prescription Drug User Fee Act (PDUFA)

c. Pediatric Research Equity Act (PREA) December 2003

d. Drug Supply Chain Security Act (DSCSA)

4. Federal Register:

a. Content and Format of Labeling for Human Prescription Drugs and Biological Products, Requirements for Pregnancy and Lactation Labeling

(commonly referred to as the Pregnancy and Lactation Labeling Rule [PLLR]), December 2014. 79 FR 72064

b. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, (commonly referred to as the Physician Labeling Rule [PLR]), January 2006. 71 FR 3922

c. Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format (commonly referred to as the Electronic Labeling Rule); December 2003. 68 FR 69009

d. Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule; February 26, 2004 (Volume 69, Number 38). 69 FR 9120

5. Prescription Drug Labeling Resources

6. Guidance:

a. Guidance for Industry: Providing Regulatory Submissions in Electronic Format- Content of Labeling

b. Guidance for Industry: An Acceptable Circular of Information for the Use of Human blood and Blood Components

c. Guidance for Industry; Contents of a Complete Submission for the Evaluation of Proprietary Names

d. Guidance for Industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements

e. Draft Guidance for Industry: Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format

f. Guidance for Industry: Product Identifier Requirements under the Drug Supply Chain Security Act – Compliance Policy

g. Guidance for Industry: Bar Code Label Requirements Questions and Answers

h. Guidance for Industry: Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers

i. Guidance for Industry: Nonproprietary Naming of Biological Products

j. Draft Guidance for Industry: Nonproprietary Naming of Biological Products: Update

k. Guidance for Industry: Pediatric Information Incorporated into Human Prescription Drug and Biological Product Labeling

7. SOPPs:

a. SOPP 8401: Administrative Processing of Original Biologics License Applications (BLA) and New Drug Applications (NDA)

b. SOPP 8001.4: Review of Proprietary Names for CBER Regulated Products

c. SOPP 8401.2: Administrative Processing of BLA and NDA Supplements

d. SOPP 8401.7: Action Package for Posting

e. SOPP 8403: Issuance, Reissuance, and Voluntary Revocation of Biological Product Licenses

f. SOPP 8411.1: Administrative Handling and Review of Annual Reports for Approved Biologics License Application (BLAs)

g. SOPP 8419: Section 505(o)(4) Required Safety Labeling Changes (SLCs)

h. SOPP 8421: Complying with Requirements under the Pediatric Research Equity Act (PREA)

i. SOPP 8426: Assignment of Biological and Drug Product Proper Names and Biological Suffixes

X. History

Written/ Revision	Approved	Approval Date	Version Number	Comment
Valencia	Martha Monser, Regulatory Review Document Lead	May 21, 2026	11	Re-added policy statement that was deleted in V10 regarding applicant to amend open labeling supplements with changes approved in another supplement. Re-ordered policy items.

Written/ Revision	Approved	Approval Date	Version Number	Comment
Valencia	Martha Monser, Regulatory Review Document Lead	March 12, 2026	10	Updated throughout for current policies and procedures.
Raza	Reviewed by RRDL Coordinator	January 31, 2025	9	Technical Update to replace the term “gender” with the term “sex”
Monser	N/A	December 11, 2020	8	Technical Update for retirement of EDR and replacement with CER and to replace/remove “database” with “system”
Monser	Reviewed by Job Aid Coordinator	November 21, 2019	7	Technical Update to correct hyperlinks and typographical errors, update references and update to current format/font.
Monser	Chris Joneckis, PhD	June 17, 2018	6	Revised to remove request for paper copies of carton/container labeling, to add DSCSA info, to cover POL/IFU and updated throughout
Monser, LSC	Chris Joneckis, PhD	Jan 18, 2016	5	Revised to include Pregnancy and Lactation Labeling Rule
Dixon, Perkins	Robert Yetter, PhD	March 21, 2012	4	Revised to include Bar Code information
Rehkopf/RMCC	Robert Yetter, PhD	Oct 13, 2011	3	Update to new format and processes
L. Falk/RMCC	Robert, Yetter, PhD	Mar 20, 2008	2	Update to include Physician’s Labeling Rule; Submission of labeling in Structured Product Labeling Format
	Robert Yetter, PhD	Dec 23, 2002	1	Original version of SOPP