OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

FINAL PRINTED LABELING AND ELECTRONIC PRINTED LABELING

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I. PURPOSE.

This document provides information on the statutory and regulatory requirements for final printed labeling (FPL) for new animal drug applications and describes how the Office of New Animal Drug Evaluation (ONADE) implements those requirements. It also contains information on the technical requirements for electronic final printed labeling (eFPL) submitted through FDA's electronic submissions gateway and CVM's electronic submission system (eSubmitter).

II. STATUTORY AND REGULATORY REQUIREMENTS

A. Statutory Requirements

Per the Federal Food, Drug and Cosmetic Act Section 512(d)(1)(F), FPL must be submitted with all applications:

"Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug….Such person shall submit to the Secretary as part of the application…(F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; …"

B. Regulatory Requirements

The Code of Federal Regulations, 21 CFR 514.1(b)(3)(vi), based on the statute reads as follows:

"Labeling – Draft labeling may be submitted for preliminary consideration of an application. Final printed labeling will ordinarily be required prior to approval of an application. Proposed advertising for veterinary prescription drugs may be submitted for comment or approval…."

III. HOW WE IMPLEMENT THE STATUTORY AND REGULATORY REQUIREMENTS[1]

In order to meet the statutory and regulatory requirements, FPL must be submitted as part of an (A)NADA.

A. FPL Submitted with the Application

If a sponsor chooses to submit FPL[2] with their original, original abbreviated, or supplemental application, then that FPL MUST be complete in all aspects of the labeling and meet all the requirements outlined in Section IV below. However, most sponsors choose to submit facsimile labeling with their application. In doing so, they will be required to submit FPL post-approval, prior to marketing, with another submission (N-G-FL or A-G-FL).

B. FLP Not Submitted with the Application

If FPL is not submitted with the initial application that was approved, then the sponsor is required to submit FPL prior to marketing. This requirement can be met by submitting the FPL within an N-G-FL or A-G-FL submission. A submission of FPL submitted after approval should also include a certification.[3]

C. Labeling Submitted with Supplemental Application

Submission of any supplement to an approved application that includes labeling changes must include a copy of the labeling. If the labeling that is submitted does not conform to the FPL standards listed in Section IV below, then the sponsor must submit FPL as an amendment or submit an N-G-FL or A-G-FL submission following approval of the supplemental application.

D. Labeling in Investigational File

An investigational new animal drug (INAD) file is typically used to submit the various technical sections to support the approval of a new animal drug application (NADA). Likewise, a generic investigational new animal drug (JINAD) file is typically used to submit technical sections to support approval of an abbreviated new animal drug application (ANADA) or generic new animal drug. The investigational file and application are linked, but are separate administrative files. Submitting labeling information to an investigational file (e.g. Labeling technical section) does not satisfy the requirements of the statute with regard to submitting FPL with applications

IV. FPL VS FACSIMILE LABELING

A. Determining if Labeling is FPL

CVM makes the determination if submitted labeling meets the requirements of FPL. If the labeling is incomplete in any way or there are errors, it is considered facsimile. Labeling that is complete, free of errors, and conforms to the requirements listed below will be considered FPL.

[1] These requirements are identical for generic approvals under the generic investigational new animal drug (JINAD) files and abbreviated new animal drug applications (ANADA).
[2] Reminder to update Volume 0 with the FPL reference
[3] See P&P 1243.2180 for more information about certifications.

Reviewers do not need to change any STARS coding based on the assessment of whether the labeling is FPL or facsimile.

B. Content Requirements

1. Facsimile labeling is draft labeling and may contain incomplete information at the time the labeling is submitted, such as the omission of the (A)NADA number. Facsimile labeling must contain all the required content of labeling to be reviewed and contain all components of labeling impacted by the changes/approval.

2. FPL must be an exact representation of the marketed labeling [including (A)NADA number]. All labeling affected by the approval must be submitted in an FPL submission.

3. Blue Bird labels and Veterinary Feed Directive (VFD) forms should meet all the technical requirements listed below, but do not need to be categorized as FPL or facsimile. Note: VFD forms are not considered labeling.

C. Technical Requirements

1. File Format

   Because ONADE accepts electronic submissions via eSubmitter, FPL must be submitted in an electronic format (eFPL). Therefore, copies of labeling must be submitted in PDF format. The PDF files should be digital native (created electronically, not scanned copies). Any file that does not appear to be a scanned copy of the label can be assumed to be a digital native copy. Ideally, the PDF file consists of native “soft proofs” that are routinely used by printing companies to print the sponsor’s new animal drug labeling.

   Soft proofing is a catch-all phrase for proofing files on a monitor rather than using a paper proof. A soft proof allows one to simulate on a computer monitor how the design will appear when reproduced or printed. Soft proofs are PDF files created from the native-format design document – QuarkXPress, Adobe InDesign, Adobe Illustrator, CorelDRAW, etc.

2. Image Size

   The PDF should depict the label at 1:1, i.e., 100% size, life-sized. If a 1:1 ratio is not realistic due to the size of the label, a scale can be used; however, the scale must be specified. When viewed at 100% zoom with a properly-adjusted PDF viewer, the label should be actual size on the monitor.

   As long as each labeling component is embedded in a PDF file at 100% (1:1), Adobe® Acrobat® provides a variety of tools for judging the appearance a label at “life size.” Horizontal and vertical rulers are available in Acrobat by viewing the Analysis toolbar, selecting the Measuring Tool, right-clicking anywhere on the labeling, and selecting Show Rulers from the menu. The tool can also show measurements from one point to another. Right-clicking anywhere on one of the rulers will allow the user to select the unit of measurement. You should use the rulers in Adobe to measure the size and not hold an actual ruler up to your monitor to measure, due to the variability in displays.

3. Legend

   The labeling file should specify the colors used in the artwork, e.g., spot colors (PANTONE®), 4-color process (CMYK), etc., a description of the colors, and the printing process that will be used to produce the actual printed labels. This information should be used to help determine how the actual colors on the printed label will appear. In most cases this is just supporting information; however, there may be a case where having the exact colors is important. That determination should be made by the reviewer.

4. Description

   A text description of the label and physical media such as finishing, folding, binding, embossing, stock weight and color, and material should be included in the submission or designated in the PDF file.

5. Photographs

   Photographs are not required and will not be the basis for review or approval. Photographs tend to have poor resolution and certain materials (e.g., foil pouches) are poorly represented. However, if reviewers determine that photographs are helpful, they may request them from sponsors on a case by case basis.

V. AT RISK MEDIA

"At risk media" is any media that has unique properties that make it difficult to review on a computer monitor. Review staff should request additional information from sponsors if the information provided is not sufficient to make an informed decision concerning the approval of the labeling submitted.

VI. REFERENCES

Section 512 of the Federal Food, Drug and Cosmetic Act

Code of Federal Regulations (Title 21)

Part 514 – New Animal Drug Applications

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.2180 Certifications for New Animal Drug Submissions and Applications

VII. VERSION HISTORY

January 20, 2017 – Original version. Posted to ONADE Policy Page

July 31, 2019 – Policy converted into an Office of New Animal Drug Evaluation Policy and Procedure document.

April 27, 2021 – Quality system review completed on the document to determine if any updates were necessary. One minor update was made in the reference section.

August 11, 2023 - Quality system review conducted of the document and no updates or revisions were necessary at this time. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.