OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

CERTIFICATIONS FOR NEW ANIMAL DRUG SUBMISSIONS AND APPLICATIONS

I. PURPOSE

This document explains:

- when certifications are required
- what information is contained in a certification
- what types of certifications may be submitted
- how certifications are reviewed by the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM)

II. SUBMISSION TYPES THAT REQUIRE CERTIFICATION

A certification accompanies information that is intended to support the approval of a/an:

- new animal drug application (NADA) as required under Title 21, Part 514.1 of the Code of Federal Regulations (CFR);
- abbreviated new animal drug application (ANADA) as required under section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and/or
- application for conditional approval (CA) as required under section 571(a)(2) of the FD&C Act.

Therefore, any submission of information intended to support the approval of an application (or any amendment to such a submission) needs a certification, including:

- submissions to investigational files (i.e., investigational new animal drug (INADs) and generic investigational new animal drug (JINADs) files) that support a single technical section, e.g., data submissions (P submissions), minor technical section submissions (M submissions);
- original applications (NADA, ANADA, or CA), supplemental applications (A and C submissions), and reactivated application submissions (E and R submissions);

- final printed labeling that was not submitted as part of the original or supplemental NADA or ANADA application but is required to be submitted prior to marketing/distribution of the animal drug (G submissions);

- Minor Changes and Stability Reports (MCSRs) submitted to an A(NADA) application (B submissions) and submissions that reactivate these reports (F submissions); and

- master files (Public Master Files (PMF) or Veterinary Master Files (VMF)) that are used to support multiple other applications or files (A or C submissions).

Submissions that do not directly support approval do not need a certification. For example, a certification is not needed for protocols (E submissions), data submitted to support a protocol or meeting (H submissions), notices of claimed investigational exemption (B submissions), requests for investigational food-use authorization (O or D submissions), categorical exclusion requests for investigational use of the drug (X submissions), or requests for meetings (Z submissions).

III. CERTIFICATION CONTENTS

The sponsor's certification is critical because reviewers at the CVM rely on the accuracy of the submitted data and information when evaluating each submission towards the approval or conditional approval of a new animal drug. Therefore, when signing the certification, the sponsor guarantees that:

- The submission contains true, accurate, and complete information;

- All copies (paper and electronic) of the submission are identical;

- For any information submitted by reference to a master file, investigational file, or application, the reference was made with the belief that the information contained in the referenced file is true, accurate and complete;

- No person debarred under the FD&C Act was used in any capacity related to the submission; and

- They are aware of consequences of supplying false information.

With the certification, the sponsor also agrees to submit safety update reports, comply with all applicable statutes and regulations, not market the drug until final determination of scheduling under the Controlled Substances Act (if applicable), and notify FDA of any change to the conditions of the approval.

The certification must be dated and signed by a responsible official, e.g., the sponsor, authorized attorney, or consulting agent. If the applicant or the authorized representative does not reside in or have a place of business in the United States (U.S.), the application must also be countersigned by an authorized agent or official residing or maintaining a place of business within the U.S., i.e., the U.S. agent.[1] The name and address of the U.S. agent must also be provided on the certification.

[1] 21 CFR 514.1(a) and P&P 1243.2020

IV. CERTIFICATIONS FOR PAPER AND ELECTRONIC SUBMISSIONS

The Animal Drug User Fee Act and Animal Generic Drug User Fee Act of 2018, amended the FD&C Act to require the electronic submission of all applications and submissions under sections 512(b) and 571, using the eSubmitter tool through CVM's Electronic Submissions System. CVM/ONADE no longer accepts paper submissions except under limited circumstances.[2]

A. Electronic Submissions

When a sponsor submits data or information electronically using eSubmitter, completion of the 356v is not necessary.[3] The eSubmitter software contains a template to help the sponsor input necessary information for ONADE submission review, replacing the 356v. The sponsor must fill out all the fields in the eSubmitter report (to the best of their knowledge) regarding the product description (e.g., target species, proprietary name, established name, proposed indication(s), dosage form, dose or dose range, duration, frequency, marketing status and submission content). In doing so, the sponsor is certifying that the data or information submitted using eSubmitter contains true, accurate, and complete information in the same way to completing a 356v.

eSubmitter Certification Text:

I certify that:

- I have personally reviewed this submission (or received assurances from qualified personnel) and determined that this submission and all supporting data, to the best of my knowledge and belief, are true, accurate, and complete,
- All copies (paper or electronic) of the submission are identical,
- For any information submitted by reference to a master file, investigational file, or application, the reference was made with the belief that the information contained in the referenced file is true, accurate, and complete,
- The services of any person debarred under section 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act have not been used in any capacity related to this submission, and
- I am aware there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing and willful violations (18 U.S.C. § 1001).

If this application is approved, I agree:

- To submit safety update reports as requested by FDA under its statutory authority or as provided for by regulation,

[2] See P&P 1243.3002
[3] See additional information regarding the FDA eSubmitter tool at https://www.fda.gov/industry/fda-esubmitter

- To comply with all applicable statutes and regulations that apply to approved applications,
- Not to market this drug product until the Drug Enforcement Administration makes a final scheduling decision if this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, and
- To notify FDA of any change to the conditions established in this approval.

Although documents can be uploaded as file attachments to the eSubmitter report, the information provided by the sponsor in the electronic eSubmitter report takes precedence over information included in the attached files.

B. Paper Submissions

When the sponsor submits data or information to CVM in paper, i.e., not electronically using eSubmitter, the Form FDA 356v (356v) must accompany any NADA, ANADA, CA, or master file. The 356v should also be included with submissions to an INAD or JINAD that support a technical section. In the 356v, the preparer (i.e., manufacturer or sponsor of a new animal drug) should include all the information necessary to identify the drug product that is the subject of the submission.

V. REVIEW OF SPONSOR CERTIFICATIONS BY CVM

Within the first few days of receipt of a submission or application, reviewers at CVM will review the 356v or eSubmitter report and conduct a cursory review of the submission contents to determine whether the submission is acceptable for review, filing, or other administrative tasks as deemed appropriate for the submission type.[4] If the submission is considered acceptable for review or filing, but the certification is not included (in a 356v for paper submissions only), has errors, is incomplete, or contradicts the information provided in the paper submission or attached eSubmitter files; CVM may request the sponsor amend the submission or application to include a completed 356v or corrected eSubmitter form.[5] The reviewer will discuss the deficiencies with their team leader to determine whether the errors or missing information are of significance.[6] If the errors do not necessitate an amendment, CVM may contact the sponsor, via email or telephone, to inform them of the noted errors so the sponsor can avoid making the same errors in future submissions.

It is important to note that the software used to create the fillable 356v PDF report does not allow the user to type symbols on the form. Symbols, such as a trademark symbol, can be copied and pasted into the form from other documents. Because of this limitation, the proprietary name field may or may not contain the requested symbols. CVM would not request an amended 356v due to the absence of a symbol. However, all documents accompanying the 356v should identify the proprietary name consistently. In the event that there is inconsistency throughout the 356v and the accompanying submission, CVM will contact the sponsor to confirm the correct way to represent the proprietary name in internal review documents and in correspondences with the sponsor and have them amend their certification. When product labeling is finalized, the proprietary name must

[4] See P&P 1243.2050 and P&P 1243.3100
[5] See P&P 1243.3026
[6] See ONADE Policy document “Inconsistent or Missing eSubmitter Information Policy”

be accurately represented, with or without symbols, as appropriate, in all approved labeling, reviews, letters, and 356v or eSubmitter forms.

VI. REFERENCES

Statutes

Federal Food, Drug, and Cosmetic Act

§512 New Animal Drugs

§571 Conditional Approval of New Animal Drugs for Minor Use and Minor Species

Code of Federal Regulations (Title 21)

Part 514 - New animal drug applications

CVM Program Policies and Procedure (P&P) Manual – ONADE Reviewer's Chapter

1243.2020 United States (U.S.) Agents

1243.2050 Refuse to File and Refuse to Review

1243.3002 Handling and Rejecting Paper Applications and Submissions

1243.3026 Assessing Submission Quality and Amending and Resetting the Clock on Submissions

1243.3100 ONADE Refuse to Review (RTR) and Refuse to File (RTF) Assessment of Submissions and Applications that Contain Data

A list of all FDA forms is posted on the fda.gov website at: https://www.fda.gov/about-fda/reports-manuals-forms/forms

FDA FORM 356v is posted on FDA.gov website at: https://www.fda.gov/media/129347/download

Additional information regarding the FDA eSubmitter tool is posted on the fda.gov website at: https://www.fda.gov/industry/fda-esubmitter

VII. VERSION HISTORY

November 16, 2001 – Original version

July 1, 2009 – Updated to reflect changes in the revised 356V and to clarify the review procedure.

July 30, 2015 – Updated to further clarify the purpose of the 356V and the review procedure, and to reflect implementation of submitting information electronically (eSubmitter).

July 19, 2019 – Updated to current P&P template format. Updated FDA.gov URL links to new directed links due to migration of new FDA.gov Website. Title changed to Certifications for New Animal Drug Submissions and Applications. No other updates needed.

April 29, 2021 – Updated language with regard to electronic submission requirements in section IV to reflect CVM's full implementation of the requirement to make submissions electronically and to add references to P&P in the reference section.

November 29, 2023 – The cyclical quality management review of the document was completed, and no substantive edits were necessary. The document was placed into the current office template and format.