OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

NEW ANIMAL DRUG APPLICATION CERTIFICATIONS

I. Purpose

The purpose of this document is to explain:

- 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 (FFDCA); and/or
- Application for conditional approval (CA) as required under section 571(a)(2) of the FFDCA.

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

- Submissions to investigational files (INADs and JINADs) 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).
- 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).

A certification should not accompany submissions that do not directly support approval. 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 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 Federal Food, Drug, and Cosmetic Act (FFDCA) 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.

IV. Certifications for Paper and Electronic Submissions

a. Paper Submissions

In accordance with section 512(b)(1) of the FFDCA, when the sponsor submits data submissions to CVM in paper, i.e. not electronically through eSubmitter, the 356V must accompany any NADA, ANADA, or CA. The 356V should also be submitted with submissions to an investigational new animal drug file (INAD) or generic investigational new animal drug files (JINAD) that support a single technical section. In the 356V, the preparer, i.e. manufacturer or sponsor of a new animal drug, should include all of the information necessary to identify the drug product that is the subject of the submission.

b. Electronic Submissions

When a sponsor submits a data submission electronically using eSubmitter[2], completion of the 356V is not necessary. 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 of 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 submitted through eSubmitter contains true, accurate, and complete information in a similar way to filling out 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 are true, accurate, and complete to the best of my knowledge and belief, • For any information submitted by reference in this submission, I/we have submitted to FDA documentation granting the right of reference and I/we have confirmed to the best of our ability that the information contained in the referenced file is true, accurate, and complete, • No services of any person debarred under section 306(a) of the Federal Food, Drug, and

[1] 21 CFR 514.1(a)

[2] See additional information regarding the FDA eSubmitter tool at http://www.fda.gov/forindustry/fdaesubmitter/default.htm

Cosmetic Act have 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). • Further, I agree: To comply with all applicable statutes and regulations governing the investigational use and approval of new animal drugs, • Not to market this drug product until the Drug Enforcement Administration makes a final scheduling under the Controlled Substances Act, and • To notify FDA of any change to an approved application. •

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.

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 content to determine whether the submission is acceptable for review, filing, or other administrative tasks as deemed appropriate for the submission type. 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 volumes or attached eSubmitter files; CVM may request that the sponsor amend the submission or application to include a completed 356V or corrected eSubmitter form. The reviewer will discuss the deficiencies with their team leader to determine whether the errors or missing information are of significance. 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 would 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 the certification. When product labeling is finalized, the proprietary name must be accurately represented, with or without symbols, as appropriate, in all approved labeling, reviews, letters, and 356V or eSubmitter forms.

VI. References and Related Documents

Statutes
Federal Food, Drug, and Cosmetic Act
§512 New Animal Drugs
Code of Federal Regulations (Title 21)
Part 514 - New animal drug applications

A list of all FDA forms is posted on the fda.gov website at:
http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm

FDA FORM 356V is posted on the fda.gov website at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/UCM048749.pdf

Additional information regarding the FDA eSubmitter tool is posted on the fda.gov website at: http://www.fda.gov/forindustry/fdaesubmitter/default.htm

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).