The Form FDA356v

Q: Is the Form FDA 356v required when I submit using the electronic eSubmitter tool?
A: No. The Form FDA 356v is only required when submitting in paper.

Q: What is Form FDA 356v?
A: If data or information being submitted to FDA is required under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) or 21 CFR 514.1 to be submitted as part of a new animal drug application, or is required under section 512(n)(1) of the act to be submitted as part of an abbreviated new animal drug application, or is required under section 571(a)(2) to be submitted as part of an application for conditional approval, it should include Form FDA 356v. The 356v should be included with any paper submission of information to support an application (or any amendment to such a submission), including:

- Submissions to investigational files (INADs and JINADs) that supports a single technical section (this includes submissions of data ('P' submission type) and minor technical section submissions ('M' submission type))
- Original applications (NADA, ANADA, or application for conditional approval) and their supplements ('A' and 'C' submission types) and submissions that reactivate these applications ('E' and 'R' submission types)
- Final printed labeling that was not submitted as part of the application (NADA or ANADA), but is required to be submitted prior to marketing an approved new animal drug ("G' submission type)
- Minor Changes and Stability Reports (MCSRs) submitted to an application (NADA or ANADA) ("B" submission type)
- Master files (Public Master Files or Veterinary Master Files) ("A" or "C" submission types)

A 356v should not accompany submissions that do not directly support approval, e.g., protocols ('E'), notices of claimed investigational exemption ('B'), requests for food-use authorization ('O' or 'D'), and requests for meetings ('Z').

Q: Where can I find Form FDA 356v?
A: You can find it from FDA's forms page (http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm) or CVM's (www.fda.gov/AnimalVeterinary) internet pages.

From the Center for Veterinary Medicine internet page, you can navigate to the form by:

- Selecting the Development Approval Process Page. http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/default.htm
- Then select the New Animal Drug Applications page. http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/NewAnimalDrugApplications/default.htm
- On the New Animal Drug Applications page the link to the 356v is on the left hand side under the Resources for You area.

The direct link to the 356v is http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/UCM048749.pdf.

If you have trouble loading the form 356v, download the latest version of Adobe Reader, i.e., 9.0, which is free, and try opening the form again. If sponsors still report problems, contact the Policy Team staff.

Q: How do I fill out the 356v?
A: Pages 4 through 6 of the form provide detailed instructions for completing and submitting Form FDA 356v.

Q: **What are the significant changes to the 356v from previous versions?**
A: There are many changes that will help CVM process submissions. Among other changes, the form:

- Recognizes that many submissions are phased submissions in support of an application and provides submission content boxes that allow a sponsor to check the appropriate box for the technical section their submission is intended to support.
- Provides space to include information relevant to the submission of abbreviated new animal drug applications.
- Adds a new check box for applications for conditional approval.
- Asks the sponsor to indicate whether the new animal drug has been designated and, if it has been designated, the date of designation.

Q: **If I am submitting information in support of an application to an INAD file, why are the citations to Part 514 or the Federal Food, Drug, and Cosmetic Act?**
A: CVM's phased review process allows a sponsor to submit parts of an application to an INAD file. Because the content of the submission supports an application, the citations are to 21 CFR Part 514, which describes the information that must be submitted to support a new animal drug application. Because there are no final regulations that describe the information that must be submitted in support of an abbreviated new animal drug application or an application for conditional approval, the citations in the form point directly to FDA's statutory authority under the Federal Food, Drug, and Cosmetic Act to require certain information in support of such applications.

Q: For Type A medicated articles, what information should be entered in the dose or dose range field under "Product Description" - the Type A concentration or the concentration in the feed?
A: The dose or dose range should reflect the dose or dose range of the form of the drug that is actually administered to the animal, i.e., the Type C medicated feed. A dose or dose range should be provided for each species for which the drug is intended for use. If there is not enough space on the form, the applicant may include and reference an attachment.