
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

NEW ANIMAL DRUG APPLICATION, FORM FDA 356V

Link: Form FDA 356V

I. PURPOSE

This Guide discusses the requirement for submission of the current version of Form FDA 356V with new animal drug applications. Form FDA 356V was substantively modified in 1998. Between November 1998 and July 31, 2001, the date on which the OMB clearance expires, copies of previous versions of the form should not be accepted from the regulated industry. Forms with OMB expiration dates of either 2001 or 2004 are acceptable. No substantive changes were included in the latest revised Form 356V. The guide also discusses the requirement for inclusion of a debarment certification in all applications for approval of a drug product.

II. REVIEW PROCEDURE

A current Form FDA 356V should be submitted with original New Animal Drug Applications, Abbreviated New Animal Drug Applications, amendments to unapproved applications, amendments to supplemental applications, and supplements to approved applications, as well as special changes as covered under 21 CFR 514.8(e). The applicant, an authorized attorney, agent, or official must sign the application. If the applicant or the authorized representative does not reside or have a place of business within the United States, the application must also provide the name and address of and be countersigned by an authorized agent or official residing or maintaining a place of business within the United States. Applications (as described above) not accompanied by a signed 356V should be rejected, and the applicant should be informed by letter of the reason for rejection.

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

Important aspects of the Form FDA 356V include:

- Full identification of the application/applicant
- Identification of submitted material
- Debarment certification
- False Statement warning

Section 306 (K) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that any application (original or supplement) filed after June 1, 1992, must include a debarment certification statement certifying that the applicant did not and will not use, in any capacity, the services of any person debarred under section 306 of the Act, in connection with the application. Therefore, a supplement to any original application approved prior to June 1, 1992, which supplement is filed after June 1, 1992, must also contain a debarment certification. Because post-1993 versions of the Form FDA 356V include the necessary certification statement, the certification requirement is fulfilled if the applicant or his authorized representative signs and submits Form FDA 356V.

III. REFERENCES

Federal Food, Drug, and Cosmetic Act, sections 306 and 512

Code of Federal Regulations 21 CFR 514, New Animal Drug Applications

ATTACHMENT: Form FDA 356V