

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0006]

OMB

Display Date	<u>5-7-01</u>
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Certifier	<u>TA?</u>

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Animal Drug Application, Form FDA 356 V

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drug Application, Form FDA 356 V— 21 CFR Part 514 (OMB Control No. 0910-0032)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act) for the approval of new animal drugs that are safe and effective. Section 512(b) of the act (21 U.S.C. 360b(b)) requires that a sponsor submit and receive approval of a new animal drug application (NADA), before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. The NADA must contain, among other things, safety and effectiveness data for the drug, labeling, a list of components, manufacturing and controls information, and complete information on any methods used to determine residues of drug chemicals in edible tissues. While the NADA is pending, an amended application may be submitted for proposed changes. After an NADA has been approved, a supplemental application must be submitted for certain proposed changes, including changes beyond the variations provided for in the NADA and other labeling changes. An amended application and a supplemental application may omit statements concerning which no change is proposed. This information is reviewed by FDA scientific personnel to ensure that the intended use of an animal drug, whether as a pharmaceutical dosage form, in drinking water, or in medicated feed, is safe and effective. The respondents are pharmaceutical firms that produce veterinary products and commercial feed mills.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.1 and 514.6	190	8.33	1,582	211.6	334,751
514.8	190	8.33	1,582	30	47,460
514.11	190	8.33	1,582	1	1,582
Total					383,793

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the burden hours required for reporting are based on fiscal year 1999 data. The burden estimate includes original NADAs, supplemental NADAs, and amendments to unapproved applications.

Dated: 5/2/01

May 2, 2001.



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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