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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N -0431]

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Certifier A. Corbin

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

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

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (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:

DL0727 2006N.0431

112

**Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR 514.4(a)  
(OMB Control Number 0910–0356)—Extension**

Section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(d)(1)(E)), requires FDA to issue an order refusing to approve a new animal drug application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 21 CFR 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine (CVM).

CVM is continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. The Center continues to look at what information can be submitted electronically and will permit electronic submission of data to NADA files as technology and resources permit.

In the **Federal Register** of November 2, 2006 (71 FR 64535), FDA published a 60-day notice in the **Federal Register** soliciting public comment on the proposed collection of information collection requirements. In response to that notice, no comments were received.

The likely respondents for this collection of information are sponsors of NADA applications.

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

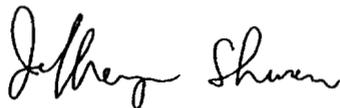
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 514.4(a)       | 190                | 4,546                         | 860                    | 632.6              | 544,036     |

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

The estimate for the annual reporting burden for this collection of information was derived from discussion with industry and agency records.

Dated: 2/7/07  
February 7, 2007.



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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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