

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier R. LEDESMA

[Docket No. 2003N-0424]

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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 (the PRA).

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

ADDRESSES: The Office of Management and Budget is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910–0356)—Extension

Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by ADAA, FDA published a regulation under § 514.4(a) (21 CFR 514.4(a)), to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADAs) and supplemental NADAs and encourages dose range labeling. Under ADAA, substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended use under the conditions suggested in its proposed labeling. Section 514.4(a) gives FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. FDA believes this regulation will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug. Table 1 of this document represents the estimated burden of meeting the substantial evidence standard.

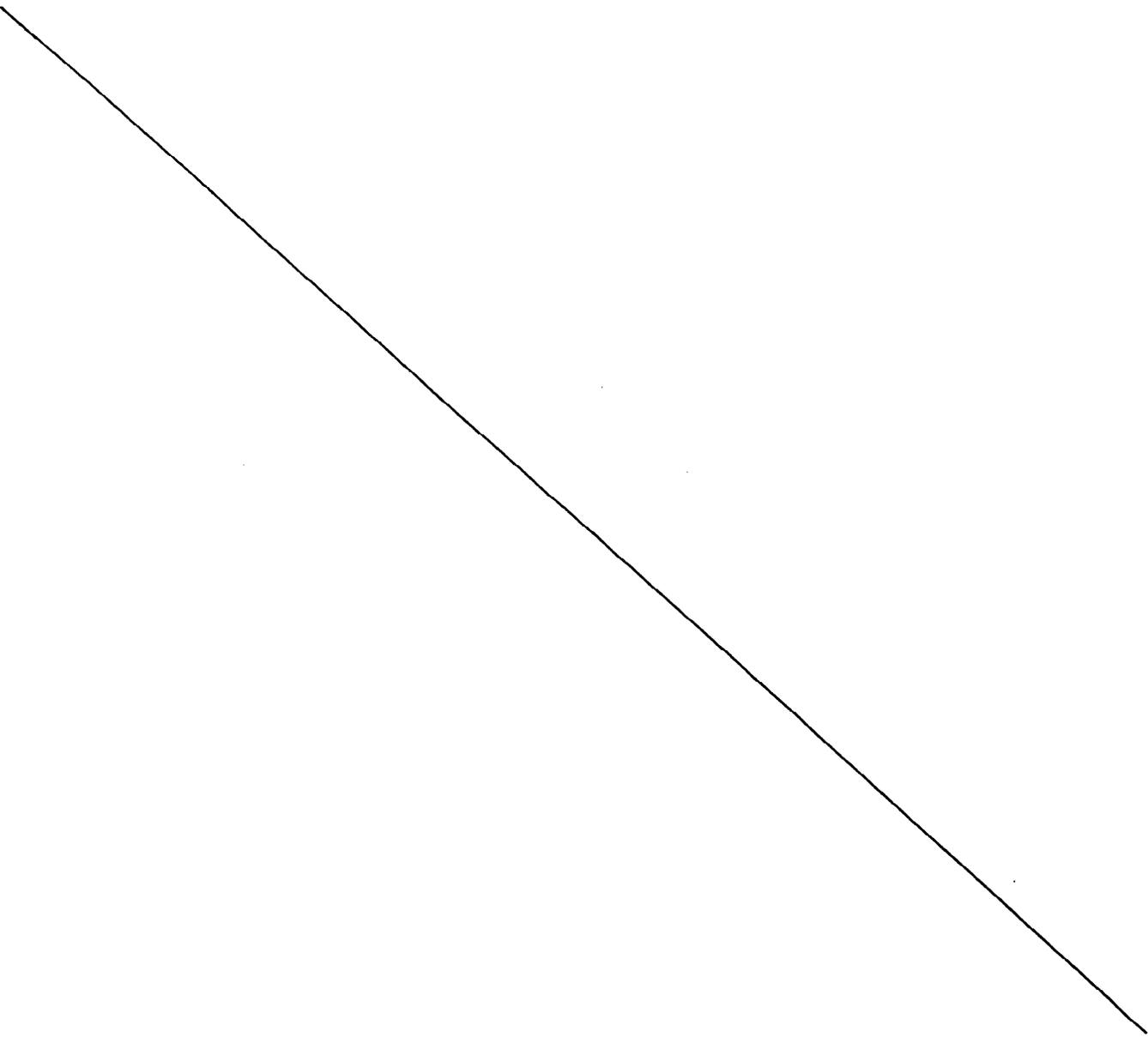
In the **Federal Register** of September 19, 2003 (68 FR 54905), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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
514.4(a)	190	4.5	860	632.6	544,036

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



Dated: 12-30-03

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December 30, 2003.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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