

DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 9-4-08
Publication Date 9-5-08
Certifier A. Corbin

[Docket No. FDA-2008-N-0312]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0325. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

OC08202

FDA-2008-N-0312

N

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.

Extralabel Drug Use in Animals—21 CFR part 530 (OMB Control Number 0910-0325)—Extension

Under part 530 (21 CFR Part 530), a veterinarian is permitted to prescribe the extralabel use of approved new animal drugs. Section 530.22 (b) of the implementing regulations permits FDA, if it finds there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to: (1) Establish a safe level for a residue from the extralabel use of the drug, and (2) require the development of an analytical method for the detection of residues above that established safe level. To date, FDA has not established a safe level for a residue from the extralabel use of any new animal drug and therefore has not required the development of analytical methodology. However, the agency believes that there may be instances when analytical methodology will be required. Thus, FDA is estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. The agency believes that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal government, or individuals.

In the **Federal Register** of June 3, 2008 (73 FR 31693), 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
530.22(b)	2	1	2	4,160	8,320

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

Dated: 8/28/08

August 28, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[Signature]
