ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Appeal	10	1	16	160

Estimated total Annual Burden Hours: 160.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Attn: ACF Desk Officer.

Dated: June 22, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–16626 Filed 6–29–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0240]

Agency Information Collection Activities; Submission for OMB 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 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 (the PRA).

DATES: Submit written comments on the collection of information by July 30, 1999.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm 10235, Washington, DC 20503, Attention: 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 section 3507 of the PRA (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 No. 0910–0325—Extension)

Description: The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Pub. L. 103–396), amended the Federal Food, Drug, and Cosmetic Act (the act), to permit licensed veterinarians to prescribe extralabel use in animals of approved human and new animal drugs. Regulations implementing provisions of AMDUCA were codified in 1996 at part 530 (21 CFR part 530). A provision of these regulations, § 530.22(b), permits FDA to establish a safe level for the extralabel use in animals of an approved human or animal drug when the agency determines there is reasonable probability that this extralabel use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding the safe level is considered an unsafe use of the drug.

In conjunction with the establishment of a safe level, FDA may request development of an acceptable residue detection method for an analysis of residues above any safe level established under this part. In some cases, the sponsor may be willing to provide this methodology, while in others, FDA, the sponsor, the U.S. Department of Agriculture (USDA), States, or a consortium of interested parties may negotiate a cooperative arrangement to develop such a methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug.

In the **Federal Register** of March 1, 1999 (64 FR 10002), the agency requested comments on the proposed collection of information. In response, FDA received one comment, which included several parts with questions. The comments and questions are listed in the following paragraphs with the agency's responses.

The comment asked: ''How will FDA determine a safe level?'' As stated in the preamble to the final rule, the agency may establish a finite safe level based on all relevant scientific information (61 FR 57732 at 57741, November 7, 1996).

The comment asked: ''What will they use?'' As stated in the rule, the agency may establish a safe level based on the lowest level that can be measured by a practical analytical method; or establish a safe level based on other appropriate scientific technical or regulatory criteria.

The comment asked: ''If data [is] not in the approved information or in [the] general domain, then how will they collect it and who will pay for it?'' As stated in the preamble to the final rule (61 FR 57732), the sponsor may be willing to provide the methodology for residue detection in some cases, while in others, FDA, the sponsor, USDA, States, or a consortium of interested parties may negotiate a cooperative arrangement to develop methodology. Conceivably, a third party who might submit such data could include a distributor or group of distributors who wish to make the drug available for extralabel use.

The comment asked: ''Will they force [a] company to collect the data to establish a safe level?'' FDA has no authority under AMDUCA or its implementing regulations to require a sponsor or any other person to collect data to establish a safe level for extralabel use if the sponsor or other person is not willing to do so. If the agency determines that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, or if no required acceptable analytical method has been developed, the agency would be permitted to prohibit extralabel use of the drug.

The comment asked: ''How much data will they demand to be collected ?'' The nature and extent of data necessary to establish a safe level or to develop an

analytical method will be determined on a case-by-case basis.

The comment asked: ''Will this rule apply to old approved drugs or just new approvals ?'' This rule applies to the extralabel use in animals of currently approved new animal and human drugs and new approvals of human and new animal drugs.

The comment asked: ''Who pays to have the analytical method developed ?'' As stated previously, the sponsor may be willing to provide the methodology for assay of residue in some cases, while in others, FDA, the sponsor, USDA, States, or a consortium of interested parties may negotiate a cooperative arrangement to development the methodology. Conceivably, a third party who might submit such data could include a distributor or group of distributors who wish to make a drug available for extralabel use.

The comment asked: ''To what extent will it have to be validated and how many tissues will it have to be validated for?'' As stated in the preamble to the final rule, methods validation is anticipated to be necessary. The number of tissues for which method validation might be required would be determined on a case-by-case basis.

The comment asked: ''If [there are] multiple approvals of [the] same active [ingredient], will they force all manufacturers to do the same work because of a different salt? If not, how will they decide who does the work?'' As was stated in the preamble to the final rule, the sponsor may be willing to provide the methodology for residue detection in some case, while in others, FDA, the sponsor, States, USDA, or a consortium of interested parties could negotiate a cooperative arrangement to develop the methodology. The third party could conceivably include a group of drug sponsors who might cooperatively submit data on behalf of all drugs with a particular active drug ingredient.

The comment asked: ''What will they do to generic approvals? Force the originator to pay?'' FDA does not comtemplate requiring a sponsor or any other person to collect data to establish a safe level for extralabel use if the sponsor or other person is not willing to do so. If the agency determines that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, or if no required acceptable analytical method has been developed, the agency would be permitted to prohibit extralabel use of the drug.

The comment asked: ''If it is FDA's plan to demand this data for all existing drug[s] that might be used in food animals, please announce your intentions.'' FDA has no plan to require the submission of data for extralabel use for all existing drugs that might be used in food-producing animals. The respondents may be sponsors of new animal drugs, State(s) or Federal Government or individuals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

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

Based on agency records and experience, the agency estimates that two methods of intermediate difficulty will be developed per year and each method may take up to two person years to develop.

Dated: June 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–16593 Filed 6–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier HCFA–R–288]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity of the utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. In particular, a statutory deadline has been missed and public harm may occur, as the result of unnecessary loss of Medicare trust fund dollars.

The Balanced Budget Act of 1997 requires the Secretary to implement up to seven competitive pricing demonstrations. Advisory committees, authorized under the Federal Advisory Committee Act (FACA), have been responsible for recommending the design of the demonstration, the sites for the demonstrations, and the manner in which the demonstrations are to be implemented. As such, this information collection was developed under the direction of the two committees and is intended for the Kansas City competitive pricing demonstration since its design is final.

Congress directed HCFA to implement the competitive pricing demonstration through the use of two FACA-compliant advisory committees composed of health care experts. Consistent with FACA requirements, all advisory committee meetings were open to the public and all affected parties were present and able to provide input. Notice of the five meetings of the Competitive Pricing Advisory Committee (CPAC) and the four meetings of the Kansas City Area