

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 93D-0398]

**Agency Information Collection Activities; Submission for OMB Review;
Comment Request; Guidance for Industry: "Assessment of the Effects of
Antimicrobial Drug Residues From Food of Animal Origin on the Human
Intestinal Flora"**

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: Stuart Shapiro, 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.

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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.

Guidance for Industry: “Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora”

In the **Federal Register** of December 27, 2001 (66 FR 66910), FDA published a 60-day notice that requested comments to the proposed collection of information. In response, the agency received two submissions containing several comments. The commenters generally supported the pathway approach outlined in the draft guidance. The comments centered on the type of information that needs to be included and the endpoints that need to be addressed. Based on suggestions contained in the comments, this final guidance will eliminate the endpoint of metabolic activity of the intestinal flora (which was proposed in the draft guidance) and will consider human data to have more weight as evidence of adverse effect on the intestinal flora, when human data is available.

Sponsors of new animal drugs must meet certain statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b). Among other things, the sponsor must demonstrate that the use of the drug is safe. Thus, when the Center for Veterinary Medicine (CVM) reviews new animal drug applications for drugs that will be used in food-producing animals, it must determine whether residues of the drug that may remain in human food derived from those animals would be harmful to humans. One possible harmful effect of residues of antimicrobial drugs that CVM considers in this determination is the possible effect of residues on human intestinal flora.

This guidance document describes the pathway approach for assessing such effects. An assessment of the safety of antimicrobial drug residues in food is a major issue that we recommend be addressed by the sponsor of a new animal drug. For residues determined to have no antimicrobial activity against representatives of the human intestinal flora, an acceptable daily intake (ADI) is recommended to be calculated based on traditional toxicological studies. The burden hours required are reported and approved under OMB control number 0910-0032. However, the guidance recommends that additional information be provided for certain drugs if an assessment of microbiological safety determines that a new animal drug produces residues in foods that are microbiologically active in the human colon. The likely respondents to this collection of information are sponsors of antimicrobial new animal drugs that will be used in food-producing animals. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Guidance	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Assessments (microbiological studies) of safety of antimicrobial drug residues that are microbiologically active in the human colon	5	1	5	14,110	70,550

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

The estimates in table 1 of this document resulted from discussions with sponsors of new animal drugs. The estimated burden includes studies, analysis of data, and writing the assessment. The number of respondents provided is based on current experience, however, the number may change in the future.

Dated: 2-21-03
February 21, 2003.



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

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