

number. OMB has now approved the information collection and has assigned OMB control number 0910-0430. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-4976 Filed 3-3-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 April 3, 2003.

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.

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 The commenters generally supported the pathway approach outlined in the draft guidance.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: February 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 13, 2003, from 8 a.m. to 6 p.m., and March 14, 2003, from 8:30 a.m. to 4 p.m.

Location: Hilton DC North—Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood or Pearlina K. Muckelvene at 301-827-1281 at least 7 days in advance of the meeting. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

Agenda: On March 13, 2003, the following committee updates are tentatively scheduled: FDA consolidation, Medical Device User Fee and Modernization Act, Clinical Laboratory Improvement Amendments waiver for human immunodeficiency, type 1 human immunodeficiency virus-1 (HIV-1) rapid tests, and the Trans Net pilot program. The committee will hear presentations, discuss, and provide recommendations on the topic of West Nile Virus testing. On March 14, 2003, the following committee updates are tentatively scheduled: Limitations on validation of anticoagulant and additive solutions to permit freezing and irradiation of red cells, and particulates in blood bags. The committee will hear presentations, discuss, and provide recommendations on the topic of extensions of the dating period for pooled platelets.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 7, 2003. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m.; and 3 p.m. and 4:30 p.m. on March 13, 2003, and between approximately 9 a.m. and 9:30 a.m.; and 10:50 a.m. and noon on March 14, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that was unable to publish this notice 15 days prior to the March 13 and 14, 2003, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-4974 Filed 3-3-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Advisory Committee for Pharmaceutical Science. This meeting was announced in the **Federal Register** of February 3, 2003 (68 FR 5297). The amendment is being made to reflect a change in the *Agenda*

portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 3, 2003 (68 FR 5297), FDA announced that a meeting of the Advisory Committee for Pharmaceutical Science would be held on March 12 and 13, 2003. On page 5298, in the first column, the second sentence in the *Agenda* portion of the document is amended to read as follows:

On March 13, 2003, the committee will: (1) Discuss and provide direction for future subcommittee: Pharmacology/ Toxicology Subcommittee; (2) receive an update on the Office of Pharmaceutical Science research projects; (3) discuss and provide comments on dose content uniformity, parametric interval test for aerosol products; (4) discuss and provide comments on bioequivalence/ bioavailability of endogenous drugs; and (5) discuss and provide comments on comparability protocols.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Fraud Alert on Telemarketing by Durable Medical Equipment Suppliers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued OIG Special Fraud Alert addressing telemarketing by durable medical equipment (DME) suppliers. For the most part, OIG Special Fraud Alerts address national trends in health care