Richard L. Espinosa, Member.
Michael H. Gibson, Member.
Mark A. Griffon, Member.
James M. Melius, M.D., Dr.P.H., Member.
Wanda I. Munn, Member.
Charles L. Owens, Member.
Robert W. Presley, Member.
Genevieve S. Roessler, Ph.D., Member.
NIOSH Staff:
Fred Blosser, Cori Homer, Stu Hinnefeld, Liz Homoki-Titus, Ted Katz, Rob McGolerick, Jim Neton, and Diane Porter.
DOL Staff:
Shelby Hallmark, Jeff Kotsch, Jeff Nesvet, and Pete Turcic.
GAO Staff:
Mary Nugent.
SC&A Staff:
Hans Behling, Joe Fitzgerald, John Mauro.
Ray S. Green, Court Recorder.

Summary/Minutes

Dr. Ziemer called to order the Advisory Board on Radiation and Worker Health (ABRWH) in closed session on December 13, 2004 at 1:30 p.m. The purpose of the closed meeting was to discuss the Individual Case Dose Reconstruction Reviews. This action will allow the ABRWH to fulfill its statutory duty to advise the Secretary of Health and Human Services on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program under EEOICPA.

General topics discussed:

- Closed session procedures.
- Case reviews presented.
- Prepared motion for consideration by the full Board regarding how to proceed with the 20 cases; the motion was approved by unanimous vote, then shared and discussed in open session by the Board on the following day. Dr. Paul Ziemer adjourned the closed session of the ABRWH meeting at 4:50 p.m. with no further business being conducted by the ABRWH.

Contact Person for More Information: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 30, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–288 Filed 1–5–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0558]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for assessing the antimicrobial resistance concerns as part of the overall preapproval safety evaluation of new animal drugs, focusing on the effect of antimicrobial new animal drugs on bacteria of human health concern.

DATES: Submit written or electronic comments on the collection of information by March 7, 2005.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern

Description: The guidance document discusses an approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. In particular, the guidance describes methodology that sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies.

Table 1 of this document represents the estimated burden of meeting the reporting requirements. The burden estimates for these information collection requirements are based on information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) NADAs for antimicrobial drugs intended for use in food-producing animals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR 514.1(b)(8) and 514.8(a)(2)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Hazard Identification (initial scoping of issues—relevant bacteria, resistance determinants, food products; preliminary data gathering)	15	1	15	30	450
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	10	1	10	1,000	1,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	10	1	10	8	80
Consequence Assessment (review ranking of human drug importance table)	10	1	10	4	40
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	10	1	10	12	120
Risk Management (discussion of appropriate risk management activities)	10	1	10	30	300
Total Burden					10,990

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

FDA estimates that on an annual basis an average of 15 NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on the number of reviews completed between October 2003 and October 2004. During that period, microbial food safety for approximately 15 antimicrobial NADAs (including original and major supplements) was evaluated. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (ANADAs), and certain supplemental NADAs.

Dated: December 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–245 Filed 1–5–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: January 26, 2005, 9 a.m. to 5 p.m., January 27, 2005, 9 a.m. to 5 p.m.

Place: DoubleTree Hotel San Diego-Mission Valley, 7450 Hazard Center Drive, San Diego, California 92108, Phone: (619) 297–5466; Fax: (619) 297–5499.

Status: The meeting will be open to the public.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national level. In addition, the Council will be holding a public hearing at which migrant farmworkers, community leaders, and providers will have the opportunity to testify before the Council regarding matters that affect the health of migrant farmworkers. The hearing is scheduled for Thursday, January 27, from 9 a.m. to 12 noon, at the DoubleTree Hotel San Diego-Mission Valley.

The Council meeting is being held in conjunction with the 14th Annual Western Migrant Stream Forum sponsored by the Northwest Regional Primary Care Association, which is being held in San Diego, California, during the same period of time.

Agenda items are subject to change as priorities indicate.

For Further Information Contact: Anyone requiring information regarding the Council should contact Gladys Cate, Office of Minority and Special Populations, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane,