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 new reporting requests. The burden estimates for these information collection requests 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) new animal drug applications (NADAs) for antimicrobial drugs intended for use in food-producing animals.

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden for this collection of information:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section 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)	5	1	5	30	150
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	5	1	5	1,000	5,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	5	1	5	8	40
Consequence Assessment (review ranking of human drug importance table)	5	1	5	4	20
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	5	1	5	12	60
Risk Management (discussion of appropriate risk management activities)	5	1	5	30	150
Total Burden					5,420

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]FDA estimates that on an annual basis an average of five NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on a review of the number of major NADA approvals that occurred between October 1997 and October 2001. During that 4-year period, an average of five antimicrobial NADAs (including original and major supplements) was approved in food-producing animals per year. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (abbreviated new animal drug applications), and certain supplemental NADAs.

Dated: September 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23941 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0124]

Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion'' dated September 2003. The guidance document provides recommendations to blood collection and transfusion facilities on reporting fatalities related to human blood and blood component collection or transfusion to FDA's Center for Biologics Evaluation and Research (CBER). The guidance announced in this notice finalizes the draft guidance of the same title dated June 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion'' dated September 2003. The guidance provides recommendations to blood collection or transfusion facilities on reporting to CBER fatalities related to human blood and blood component collection and transfusion. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2002 (67 FR 38505, June 4, 2002).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in 21 CFR 606.170(b) cited in the guidance has been approved by OMB under OMB control number 0910–0116.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23997 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Office of AIDS Research Advisory Council.

Date: October 14–15, 2003.

Time: 9 a.m. to 12 p.m.

Agenda: A Report of the Director addressing OAR initiatives. The topic of the meeting will be ''Issues in Domestic and International Clinical Trails of Therapeutic and Prevention Interventions.''

Place: National Institutes of Health, Bldg. 31, 9000 Rockville Pike, Room 6C10, Bethesda, MD 20892.

Contact Person: Jack Whitescarver, Director, Office of AIDS Research, OD, National Institutes of Health, 9000 Rockville Pike, Building 2, Room 4E14, Bethesda, MD 20892, (301) 496–0357.

Information is also available on the Institute's/Center's home page: *www.nih.gov/od/oar/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals form Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: September 11, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–23903 Filed 9–18–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Issues and Challenges in the Design and Conduct of Clinical Trials of Drugs in Pre-Term Infants and Neonates

The National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH), Department of Health and Human Services, will sponsor a working meeting to explore approaches for the design and conduct of clinical trials to foster safe and effective drug therapies in pre-term infants and neonates on March 29–March 30, 2004, at the Baltimore and Washington International Airport Marriott Hotel.

The NICHD is sponsoring the meeting in collaboration with the Food and Drug Administration, the Fogarty International Center, and other NIH institutes and centers, including the National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute of Dental and Craniofacial Research; National Institute of Diabetes ands Digestive and Kidney Diseases; National Institute of Neurological Disorders and Stroke; National Institute of Allergy and Infectious Diseases; National Institute of General Medical Sciences; National Eye Institute; National Institute of Environmental Health Sciences; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Mental Health; National Institute on Drug Abuse; National Institute on Alcohol Abuse and Alcoholism; National Institute of Nursing Research; National Human