

Violence is an important public health problem. In the United States, homicide and suicide are the second and third leading causes of death, respectively, in the 1–34 year old age group.

Unfortunately, public health agencies don't know much more about the problem than the numbers and the sex, race, and age of the victims, all information obtainable from the standard death certificate. Death certificates, however, carry no information about key facts necessary for prevention such as the relationship of the victim and suspect and the circumstances of the deaths, thereby making it impossible to discern anything but the gross contours of the problem. Furthermore, death certificates are typically available 20 months after the completion of a single calendar year. Official publications of national violent death rates, *e.g.* those in *Morbidity and Mortality Weekly Report*, rarely use data that is less than two years old. Public health interventions aimed at a moving target last seen two years ago may well miss the mark.

Local and federal criminal justice agencies such as the Federal Bureau of Investigation (FBI) provide slightly more information about homicides, but they do not routinely collect standardized data about suicides, which are in fact much more common than homicides.

The FBI's Supplemental Homicide Report system (SHRs) does collect basic information about the victim-suspect relationship and circumstances, like death certificates, it does not link violent deaths that are part of one incident such as homicide-suicides. It also is a voluntary system in which some 10–20 percent of police departments nationwide do not participate. The FBI's National Incident Based Reporting System (NIBRS) addresses some of these deficiencies, but it covers less of the country than SHRs, still includes only homicides, and collects only police information. Also, the Bureau of Justice Statistics Reports do not use data that is less than two years old.

CDC therefore proposes to start a state-based surveillance systems for violent deaths that will provide more detailed and timely information. It will tap into the case records held by medical examiners/coroners, police, and crime labs. Data will be collected centrally by each state in the system, stripped of identifiers, and then sent to the CDC. Information will be collected from these records about the characteristics of the victims and suspects, the circumstances of the deaths, and the weapons involved. States will use standardized data elements and software designed by CDC. Ultimately, this information will guide

states in designing programs that reduce multiple forms of violence.

Neither victim families nor suspects are contacted to collect this information. It all comes from existing records and is collected by state health department staff or their subcontractors. Health departments incur an average of 2.5 hours per death in identifying the deaths from death certificates, contacting the police and medical examiners to get copies of or to view the relevant records, abstracting all the records, various data processing tasks, various administrative tasks, data utilization, training, communications, etc.

The number of state health departments to be funded may be as high as 10 once FY03 cooperative agreements are awarded. Six states were funded thru FY02 cooperative agreements, and up to 4 more may be funded in 2003. NCIPC hopes to eventually fund all 50 states. Violent deaths include all homicides, suicides, legal interventions, deaths from undetermined causes, and unintentional firearm deaths. There are 50,000 such deaths annually among U.S. residents, so the average state will experience approximately 1,000 such deaths each year. The total number of burden hours are 25,000, based on 10 states participating.

Respondents	Number of respondents	No. of responses/respondent	Average burden/response (in hours)
State Health Departments (10)—Completion of case abstraction .....	1,000	1	2
State Health Departments (10)—Retrieving and refiling records .....	1,000	1	30/60

Dated: September 12, 2003.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, , Centers for Disease Control and Prevention.*

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**BILLING CODE 4162–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Biological Response Modifiers 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). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Biological Response Modifiers 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 October 9, 2003, from 8 a.m. to 6 p.m.; and on October 10, 2003, from 8 a.m. to 2 p.m.

**Location:** Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

**Contact Person:** Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the

Washington, DC area), code 12389.

Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On October 9 and 10, 2003, the committee will discuss the following topics: (1) Issues related to manufacturing data and clinical evidence to be provided in a biologics license application (BLA) for marketing approval of allogeneic islet transplantation to treat type 1 diabetes mellitus, (2) hear updates of individual research programs in the Office of Cellular, Tissue and Gene Therapies, and (3) reports of internal research programs in the Office of Cellular, Tissue and Gene Therapies.

**Procedure:** On October 9, 2003, from 8 a.m. to approximately 5:15 p.m.; and on October 10, 2003, from 8 a.m. to approximately 2 p.m., the meeting is open to the public. 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 October 2, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on October 9 and between approximately 10:30 a.m. and 11 a.m. on October 10. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 2, 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.

**Closed Committee Deliberations:** On October 9, 2003, from approximately 5:15 p.m. to 6 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

The committee will discuss a report of a review of internal research programs in the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: September 9, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-23780 Filed 9-17-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Veterinary Medicine 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 the Committee:** Veterinary Medicine 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 November 3 and 4, 2003, from 8:30 a.m. to 5 p.m.; and on November 5, 2003, from 8:30 a.m. to 1 p.m.

**Location:** The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** Aleta Sindelar, Center for Veterinary Medicine (CVM) (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4515, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On November 3, 2003, the committee will seek recommendations on the potential approval of fourth generation cephalosporins for use as therapeutic antibiotic new animal drugs for veterinary medicine. The committee is likely to consider both a specific drug product currently under review as well as the subject of fourth generation cephalosporins as a whole. On November 3 and 4, 2003, the committee will consider two animal biotechnology issues: cloning and genetic engineering. On November 4, the committee will consider a risk assessment on cloning through somatic cell nuclear transfer of animals that addresses both food and animal safety. On November 5, the committee will consider issues relating to the responsibilities of sponsors and investigators involved in genetic engineering research with food animals. The committee will review contemplated center information exchange approaches and assistance for investigators. The committee will provide feedback on the clarity of the message and the most efficient way to inform this group of investigators. Background information will be made available to committee members and the public in advance of the meeting and posted on CVM's home page at <http://www.fda.gov/cvm>. A limited number of paper copies of the background information will be available at the registration table.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on the issues pending before the committee. Written submissions may be made to the contact person by October 24, 2003. Oral presentations from the public will be scheduled between approximately 10

a.m. and 12 noon on November 3, 4, and 5, 2003. The time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person before October 27, 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. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Anna Roy, Conference Management Staff, 301-827-2947, at least 7 days in advance of the meeting.

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

Dated: September 9, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0163]

#### Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome or Exposure to Severe Acute Respiratory Syndrome; 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: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS," dated September 2003. The guidance provides revised recommendations to blood establishments for assessing donor suitability and blood product safety with respect to SARS. The guidance