are suitable for detecting melamine contamination in at-risk components down to 2.5 parts per million (ppm) to give a high degree of assurance that they are not contaminated. At this time, FDA has not established an appropriate level of melamine in drug products.

As explained in detail in the guidance, there have been repeated instances of melamine contamination in food articles, including in the U.S. market. In 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. In September 2008, FDA received reports of melamine-contaminated infant formula in China. These two incidents share the following similarities:

- Melamine, a nitrogen-based compound, was apparently added to bolster the apparent protein content in foods or in ingredients used in processed food products intended to contain protein.
- The recipients of the ingredients using a test for nitrogen content would not have been able to distinguish between melamine and the desired protein.
- Melamine contamination became public only after numerous adverse health events, including deaths, were reported and associated with the use of contaminated products.

These incidents illustrate the potential for drug components to be contaminated with melamine; therefore, it is important for drug manufacturers to be diligent in assuring that no component used in the manufacture of any drug is contaminated with melamine. As of the date of this guidance, FDA is not aware of any pharmaceuticals that are contaminated with melamine. However, because of the potential risk of drug contamination, it is important that manufacturers take steps to ensure that susceptible components are not contaminated with melamine.

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The agency is not seeking comment before implementing this guidance because of the potential for a serious public health impact if melamine-contaminated pharmaceuticals were to enter the domestic market. The guidance represents the agency's current thinking on this issue. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm*, or *http://www.regulations.gov*.

Dated: July 31, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18952 Filed 8–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Environmental Health Sciences Review Committee.

Date: August 25–26, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill Hotel, One Europa Drive, Chapel Hill, NC 27517.

Contact Person: Linda K Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18993 Filed 8–6–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket Number DHS–2008–0159]

Privacy Act of 1974; DHS/FEMA–004 Grant Management Information Files System of Records

AGENCY: Privacy Office; DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security is giving notice that it proposes to consolidate into one new system its inventory of record systems entitled, Federal Emergency Management Agency Grant Management Information Files. This system will enable the Department of Homeland Security to better administer the Federal Emergency Management Agency Disaster Recovery Assistance Program. Many Federal Emergency Management Agency grant programs collect a minimum amount of contact and grant project proposal information. The information contained in the Federal Emergency Management Agency's Grant Management Information Files is collected in order to determine awards for both disaster and non disaster grants and for the issuance of awarded funds.

DATES: The established system of records will be effective September 8, 2009. Written comments must be submitted on or before September 8, 2009.