## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Fiscal Year (FY) 2009 Funding Opportunity

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of intent to award a Single Source Grant to Link2Health Solutions, Inc.

**SUMMARY:** This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $1,038,000 (total costs) for up to one year to Link2Health Solutions, Inc. This is not a formal request for applications. Assistance will be provided only to Link2Health Solutions, Inc based on the receipt of a satisfactory application that is approved by an independent review group.

*Funding Opportunity Title:* SM–09–020.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

*Authority:* Section 520(A) of the Public Health Service Act, as amended.

*Justification:* Only an application from Link2Health Solutions will be considered for funding under this announcement. One-year funding has become available to assist SAMHSA in responding to the growing and pressing need to provide resources for individuals stressed by the nation's current economic crisis. It is considered most cost-effective and efficient to supplement the existing grantee for the National Suicide Prevention Lifeline and to build on the existing capacity and infrastructure within its network of crisis centers.

Link2Health Solutions is in the unique position to carry out the activities of this grant announcement because it is the current recipient of SAMHSA's cooperative agreement to manage the National Suicide Prevention Lifeline. As such, Link2Health Solutions has been maintaining the network communications system and has an existing relationship with the networked crisis centers.

The crisis centers that comprise the National Suicide Prevention Lifeline are a critical part of the nation's mental health safety net. Many crisis centers are experiencing significant increases in calls. The National Suicide Prevention Lifeline crisis centers require assistance to continue to play their critical role in providing support as well as emergency services to suicidal callers during these challenging economic times. In addition, the National Suicide Prevention Lifeline crisis centers are community resources that need to be utilized to reach out to those in their communities most at risk, including those currently impacted severely by the economy.

*Contact:* Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1081, Rockville, MD 20857; *telephone:* (240) 276–2321; *E-mail: shelly.hara@samhsa.hhs.gov.*

**Toian Vaughn,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. E9–18873 Filed 8–6–09; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0354]**

### Guidance for Industry on Pharmaceutical Components at Risk for Melamine Contamination; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Pharmaceutical Components at Risk for Melamine Contamination.'' This guidance provides recommendations that will help pharmaceutical manufacturers of finished products, repackers, other suppliers, and pharmacists who engage in drug compounding avoid the use of components that are at risk for melamine contamination. As of the date of this announcement, FDA is not aware of any pharmaceutical components that are contaminated with melamine.

**DATES:** Submit written or electronic comments on the guidance by October 6, 2009. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Frank W. Perrella, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4337, Silver Spring, MD 20993–0002, 301–796–3265; or

Brian Hasselbalch, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279; or

Diane Heinz, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9031.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pharmaceutical Components at Risk for Melamine Contamination.'' This guidance provides recommendations that will help pharmaceutical manufacturers of finished products, repackers, other suppliers, and pharmacists who engage in drug compounding to better control their use of at-risk components that might be contaminated with melamine. The guidance explains that the agency is recommending that at-risk components be properly tested for melamine contamination before they are used in the manufacture or preparation of drugs or drug products. This recommendation applies to nitrogen-based components.

As discussed in the guidance, FDA has posted on its Web site methods for measuring melamine contamination in foods using liquid chromatography triple quadrupole tandem mass spectrometry (LC–MS/MS) and gas chromatography/mass spectrometry (GC–MS). Although these methods have been evaluated using dry protein materials, they can also be applicable to other material, including at-risk components. Manufacturers are encouraged to validate test methods that

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.