

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.

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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