which, according to ATSDR and U.S. EPA, pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on March 6, 2008 (73 FR 12178). In addition, ATSDR has the authority to prepare toxicological profiles for substances not found at sites on the National Priorities List, in an effort to ''* * * establish and maintain inventory of literature, research, and studies on the health effects of toxic substances'' under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and as otherwise necessary to support the site-specific response actions conducted by ATSDR.

For previous versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); and December 7, 2005 (70 FR 72840). [CERCLA also requires that ATSDR initiate a research program to fill data needs associated with the substances.] Section 104(i)(3) of CERCLA [42 U.S.C. 9604(i)(3)] outlines the content of these profiles. Each profile will include an examination, a summary, and an interpretation of available toxicological information and epidemiological evaluations. This information and these data identify the levels of significant human exposure for the substance and for the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or is in the process of development. If adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to ensure the initiation of research to determine such health effects.

Although during the profile development process ATSDR considered key studies for each of the substances, this **Federal Register** notice solicits any relevant, additional studies, particularly unpublished data and ongoing studies. ATSDR will evaluate such data or studies for possible addition to the profiles, now or in the future.

The following draft toxicological profiles have been made available to the public:

Toxicological profile	CAS Number
1. Acrylamide	79–06–1
2. Carbon Monoxide	630–08–0
3. 1,3–Butadiene	106–99–0
4. Phosphate Ester Flame Retardants	78–51–3
	126–73–8
	126–71–6
	115–86–6
	13674–84–5
	13674–87–8
	115–96–8
5. Vanadium	7440–62–2

All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We seek public comment and additional information that may supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as the best means to serve public health and our clients.

Dated: December 4, 2009.

Ken Rose,

Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. E9–29345 Filed 12–16–09; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–F–0570]

Lallemand, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Lallemand, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of vitamin D_2 bakers yeast as a dual purpose nutrient supplement and leavening agent or dough relaxer in yeast-containing baked products.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9A4779) has been filed by Lallemand, Inc., c/o Dennis T. Gordon, 117 N. Welcome Slough Rd., Puget Island, Cathlamet, WA 98612. The petition proposes to amend the food additive regulations in part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of vitamin D_2 bakers yeast as a dual purpose nutrient supplement and leavening agent or dough relaxer in yeast-containing baked products.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 8, 2009.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E9–29961 Filed 12–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of noncompetitive replacement awards to Regional Health Care Affiliates.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) New Access Point (NAP) and Increased Demand for Service (IDS) funds originally awarded to Trover Health System to Regional Health Care Affiliates to ensure the provision of critical primary health care services to underserved populations in Webster and McLean Counties, Kentucky.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Trover Health System.

Original Period of Grant Support: March 1, 2009 to February 28, 2011 (NAP) and March 27, 2009 to March 26, 2011 (IDS).

Replacement Awardee: Regional Health Care Affiliates.

Amount of Replacement Awards: $1,300,000 (NAP) and $101,000 (IDS).

Period of Replacement Awards: The period of support for the replacement awards is March 1, 2009, to February 28, 2011 (NAP) and March 27, 2009, to March 26, 2009 (IDS).

Authority: Section 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.703.

Justification for the Exception to Competition

Under the original grant applications approved by HRSA, Regional Health Care Affiliates (RHCA) was identified as the provider of health care services on behalf of the Trover Health System, while Trover Health System was to serve in an administrative capacity for the grants. After the awards were issued, Trover Health System and RHCA notified HRSA that RHCA's organizational structure had changed to enable it to carry out both administrative and programmatic requirements. The two parties requested that full responsibility for the grants be transferred from Trover Health System to RHCA. RHCA provided documentation that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

Regional Health Care Affiliates will directly initiate primary health care services in Webster and McLean Counties to the more than 5,250 low income, underserved and uninsured individuals in the original service area, Webster and McLean Counties, KY, as had been proposed in funded grant applications.

Regional Health Care Affiliates can provide primary health care services immediately, is located in the same geographical area where the Trover Health System's primary health care services have been provided, and will be able to provide continuity of care to patients of the former grantee.

This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay caused by a competition. As a result, in order to ensure that critical primary health care services are available to the original target population in a timely manner, these replacement awards will not be competed.

FOR FURTHER INFORMATION CONTACT: Marquita Cullom-Stott via e-mail at *MCullom-Stott@hrsa.gov* or 301–594–4300.

Dated: December 10, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–30010 Filed 12–16–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0573]

International Conference on Harmonisation; Draft Guidance on Addendum to International Conference on Harmonisation S6; Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Addendum to ICH S6: Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1).'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides recommendations on nonclinical studies to support the safety of clinical trials and marketing applications for biotechnology-derived pharmaceuticals. The draft guidance is intended to clarify and provide greater detail to the nonclinical recommendations in the ICH guidance entitled ''S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals'' (ICH S6) published in the **Federal Register** of November 18, 1997 (62 FR 61515).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by February 1, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft 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 Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Anne M. Pilaro, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2324, Silver Spring, MD 20993–0002, 301–796–2320; or Mercedes A. Serabian, Center for Biologics Evaluation and Research (HFM–760), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5377.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics