

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-04-4003]

DDM
Display Date 7-30-04
Publication Date 8-2-04
Certifier R. LEDESMA

**Memorandum of Understanding Between the Food and Drug Administration
and the University of California, Lawrence Livermore National Laboratory**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the University of California (UC), Lawrence Livermore National Laboratory to establish the framework for collaborative research and development and emergency triage response efforts. FDA and UC Lawrence Livermore National Laboratory will work collaboratively to expedite development of methods and technologies that are needed to address Homeland Security issues.

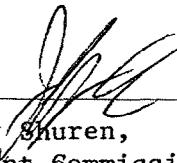
DATES: The agreement became effective February 23, 2004.

FOR FURTHER INFORMATION CONTACT: Karen A. Wolnik, Forensic Chemistry Center (HFR-CE502), Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700 ext. 181.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall

be published in the **Federal Register**, the agency is publishing notice of this MOU.

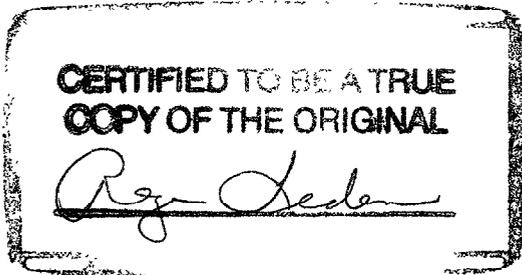
Dated: 7/21/04
July 21, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S



**Memorandum of Understanding
Between
University of California
Lawrence Livermore National Laboratory
and
United States Food and Drug Administration
Office of Regulatory Affairs
for
Collaborative Research and Development
for
Homeland Security**

I. Purpose, Objectives and Goals:

- a. Purpose.** This Memorandum of Understanding (MOU) establishes the framework for collaborative research and development and emergency triage response efforts between the University of California Lawrence Livermore National Laboratory (UC LLNL) and its Laboratories and Centers and the Food and Drug Administration (FDA) Office of Regulatory Affairs and its Laboratories on the subject of Homeland Security. Research and development efforts specifically targeted under this MOU are focused on, but not limited to, food safety and rapid risk assessment. The MOU is intended to expedite research and development of new methods and technologies that can be implemented in support of Homeland Security efforts by federal, state or local government entities as well as authorized private sector organizations to avert and/or mitigate the effects of terrorist activities in the United States.

Both UC LLNL and FDA believe that this collaboration will contribute to more efficient resource utilization, avert or minimize duplication, and accelerate method and technology advancement in the Homeland Security arena. The two organizations further believe that successful collaboration will leverage beneficial results via method and technology transfer in support of human health, while ensuring a safe food supply for the United States of America.

- b. Objectives.** FDA and UC LLNL will work collaboratively to expedite development of methods and technologies that are needed to address Homeland Security issues.
- c. Goals.**
- i. Identify method and technology needs, formulate research and development projects that address food security needs, and

establish Interagency Agreements (IAGs) or other extramural arrangements that describe how personnel and resources of FDA and UC LLNL will be effectively utilized to perform research and development projects addressing Homeland Security issues such as early detection of impending terrorist attacks or the aftermath of terrorist attacks.

- ii. Perform collaborative research and development projects in an expeditious manner.
- iii. Provide products from the research and development projects in a form and format that can be easily used and understood by the targeted public and private sector organizations involved in Homeland Security activities.

II. Background and Program Scope:

a. Background. Terrorist attacks against the United States and the consequent war on terrorism being waged by the U.S., its allies and many countries around the world have provided great impetus for the development of methods and technologies that can be utilized to detect and/or neutralize terrorist threats. One of the greatest concerns facing the United States and other nations is the deliberate use of chemical, biological, nuclear or radiological weapons by terrorist organizations. Following the tragic events of September 11, 2001, the U.S. Food and Drug Administration, the University of California Lawrence Livermore National Laboratory, and other federal agencies, as well as universities and emergency response organizations in the public and private sector, began addressing the need for new methods and technologies related to Homeland Security.

b. Program Scope. Under this MOU the two organizations – UC LLNL and FDA – will meet on an annual basis to identify areas of research and development, and emergency related to Homeland Security that can be efficiently addressed through a collaborative approach.

III. Responsibilities:

a. The Food and Drug Administration, consistent with agency regulations governing the release of information, agrees to:

- i. Work with UC LLNL to: (1) identify research and development needs in the area of Homeland Security; (2) develop, formulate and establish IAGs [this MOU will be incorporated by reference in each

related IAG] between specific UC LLNL Laboratories and Centers and one or more FDA Laboratories; and (3) describe specific research and development projects that will be jointly pursued by FDA and UC LLNL.

- ii. Participate in joint technical activities (e.g., workgroups, or scientific panels) with representatives from UC LLNL, and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.
- iii. Enter into IAGs that address research and development needs, under which FDA personnel from one or more FDA Laboratories will work cooperatively on projects of mutual interest and formulated as described above with UC LLNL as time (the Food and Drug Administration has priority) and resources permit.
- iv. In special cases and subject to approval by the Director of the appropriate FDA Laboratory, work with UC LLNL to address the research and development needs of a third party (either public or private).
- v. Assign a Management Point of Contact and Technical Lead(s) for interactions with the UC LLNL.
- vi. Provide, in cooperation with UC LLNL's Management Point of Contact, an annual executive summary report on the progress made under this MOU for each of the IAG's or other cooperative activities that are developed as part of this agreement (MOU).
- vii. Record, produce and maintain minutes of meetings as described in this MOU.

b. The University of California Lawrence Livermore National Laboratory, consistent with agency regulations governing the release of information agrees to:

- i. Work with FDA to: (1) identify research and development needs in the area of Homeland Security; (2) develop, formulate and establish IAG's [this MOU will be incorporated by reference in each related IAG] between one or more FDA Laboratories and UC LLNL Laboratories and Centers; and (3) describe specific research and development projects that will be jointly pursued by UC LLNL and FDA.

- ii. Participate in joint technical activities associated with specific IAG's (e.g., workgroups, or scientific panels) with representatives from FDA and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.
- iii. Enter into IAGs that address research and development needs, under which UC LLNL personnel will work cooperatively on projects of mutual interest and formulated as described above with FDA as time (the UC LLNL mission has priority) and resources permit.
- iv. In special cases and subject to approval by the Director of the appropriate UC LLNL Laboratory or Center, work with FDA to address the research and development needs of a third party (either public or private).
- v. Cooperate in making facilities available in cases where emergency response activities are required.
- vi. Assign a Management Point of Contact and Technical Lead(s) for interactions with the FDA.

IV. Memorandum of Understanding (MOU) Administration:

- a. **Reports.** The status of work performed (associated with specific IAG's) under this MOU will be reviewed on an annual basis. The FDA Coordinator of Counter Terrorism Laboratory Response Development/Office of Regulatory Affairs, will take the lead and be responsible for organizing meetings (planning meetings and annual meetings), developing agenda and recording results of the meetings. Minutes of the meetings will be produced by FDA and be distributed to meeting participants as well as to the Director of the appropriate FDA Laboratory and in turn the Commissioner, FDA and to the UC LLNL. A central file (retained by the FDA) will be maintained.
- b. **Information Releases:** The Associate Commissioner for Regulatory Affairs, FDA, and UC LLNL (or their designees) will jointly review and approve information regarding MOU activities (meetings, new developments, etc.) prior to public release. IAGs prepared under this agreement will stipulate specific procedures for the coordination, handling and public disclosure of information. All information disclosures concerning activities under this MOU or subsequent IAGs will comply with agency regulations governing the release of information. Where particular

information protocols apply to a particular laboratory, or network of laboratories, those protocols will be followed by both parties to this MOU.

- c. **Security Classification:** The highest security classification applied by either FDA or UC LLNL will govern the handling of information and reports under this MOU, as appropriate. The security classification and procedures will be stipulated in each IAG.
- d. **Facility Security, Health, Safety and Environmental Compliance:** When working at a host's facility, the guest employee will follow the security, health, safety and environmental policies and regulations of that facility.
- e. **Reimbursement Policy:** Each party to this agreement will handle and expend its own funds. The responsibilities assumed by each party are contingent upon funds being available from which expenditures legally may be met.
- f. **Annual Management Meetings:** UC LLNL and FDA will meet yearly to plan and coordinate research and development activities, and emergency response triage activities under this MOU. Such meetings will be held at a mutually agreed upon location and on a date that is compatible with the planning and budgeting cycle of each organization. At this meeting, recommendations for adjustments to current activities, projects, and budget priorities will be proposed and agreed upon by the Management Points of Contact for submission to the appropriate UC LLNL and FDA administrators for further action.
- g. **Semi-Annual Technical Discussion:** UC LLNL and FDA will meet twice a year to discuss technical progress under each IAG or activity. These reviews will require technical information exchange by UC LLNL and FDA Technical Leads. These meetings may include individuals from outside of UC LLNL and FDA as mutually agreed to by the respective Management Points of Contact.
- h. **Technical Lead Responsibilities:** Technical Leads for each IAG or activity will strive to engage in:
- Providing technical information exchange consistent with agency regulations governing the exchange or release of information
 - Delivering written or verbal technical evaluations of progress
 - Conducting visit to sites where research is underway
 - Organizing and Participating in technical workshops and scientist-to-scientist meetings

- Reporting on any exceptional accomplishments from, or impediments to, successful program or project execution
- Recommending improvements for the MOU activities

i. **Approvals:** All IAGs and activities conducted to carry out this MOU must be agreed to and approved by the UC LLNL and FDA prior to commencement of any technical work.

j. **Inventions and Licensing:** Activities conducted to carry out this MOU and any IAGs or other extramural arrangements may result in products or processes that are patentable or otherwise proprietary. The organization whose work results in the invention shall disclose the invention to the other organization and may then prepare, file, and prosecute patent applications. If protection is granted, the inventing organization will manage the invention in accordance with its rules and regulations subject to a government use license. Inventions resulting from joint research and development by both UC LLNL and FDA employees shall be handled as jointly agreed to at the time of the disclosure.

V. Period of Agreement:

- a. This MOU shall be effective for five years from the date of the last signature unless canceled in writing by (either/any) of the participating organizations with 90 days notice.
- b. This MOU will be reviewed annually by the Management Points of Contact to determine if any changes or amendments should be incorporated. Such changes or amendments will be formally incorporated in the MOU by mutual agreement.

VI. Names and Addresses of Parties:

University of California
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550

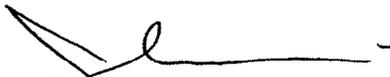
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

VII. General Provisions:

- a. Nothing in this MOU supersedes any other memorandum of understanding held by either party.
- b. This MOU in no way restricts the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.
- c. This MOU describes in general terms, the basis upon which the parties intent to cooperate. It does not create binding, enforceable obligations against any party.

VIII. Signatures:

Approved and Accepted for the Food and Drug Administration by



John M. Taylor
Associated Commissioner for Regulatory Affairs
U.S. Food & Drug Administration

4/14/04

Date

Approved and Accepted for the University of California
Lawrence Livermore National Laboratory by:



Dr. Harold Graboske, Jr
Deputy Director, Science and Technology
Lawrence Livermore National Laboratory

23 Feb 04

Date