The estimated burden associated with the information collection requirements for these provisions is 2,114 hours.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19394 Filed 9–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4007]

Memorandum of Understanding between the Food and Drug Administration, Forensic Chemistry Center and the Federal Bureau of Investigation

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 the Food and Drug Administration and the Federal Bureau of Investigation (FBI). The purpose of this MOU is to establish the general policies and procedures that will govern administrative, logistical, and operational support to FBI missions including cost reimbursable activities.

DATES: The agreement became effective December 22, 2004.

FOR FURTHER INFORMATION CONTACT:

For the FDA: Fred Fricke, Food and Drug Administration, Forensic Chemistry Center, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700.

For the FBI: David L. Wilson, Federal Bureau of Investigation Laboratory, Chemical Biological Sciences Unit, Quantico, VA 22135, 703–632–7766.

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: September 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-04-4007

MEMORANDUM OF AGREEMENT

BETWEEN

THE FEDERAL BUREAU OF INVESTIGATION

AND

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

GENERAL PROVISIONS

1. PURPOSE.

This memorandum of agreement (MOA) establishes the process that the Unites States Food & Drug Administration, Forensic Chemistry Center (FDA-FCC) and the Federal Bureau of Investigation (FBI) have mutually agreed to use to support specific tasks to be performed by each agency to execute U.S. Government (USG) commitments and obligations and necessary mission support. This MOA establishes the general policies and procedures that will govern administrative, logistical, and operational support to FBI missions including cost reimbursable activities.

2. AUTHORITY.

The authority to establish this support agreement is contained in the following references:

a. 10 U.S.C. 371 - 382.

b. 18 U.S.C. 229E.

c. 28 U.S.C. 533.

d. 42 U.S.C. 3771.

e. Presidential Decision Directive 39 (PDD-39), titled: U.S. Policy on Counterterrorism.

f. PDD-62, titled: Combating Terrorism.

g. PDD-63, titled: Critical Infrastructure Protection.

h. NSPD-17/HSPD-4: titled: National Strategy to Combat Weapons of Mass Destruction.

i. HSPD-5, titled: Management of Domestic Incidents.

3. SCOPE.

This MOA defines the relationship between FDA-FCC and the FBI Laboratory in issues of direct analytical services, co-activation/co-deployment, expert advice and counsel, work space allocation, and research and development.

a. General. This MOA establishes a relationship between FDA-FCC and the FBI. Contingent upon agreement of the FDA-FCC Director, FDA-FCC will provide scientific consultation and analytical services concerning the forensic examination of samples within respective areas of expertise. FDA-FCC will coordinate with the FBI to develop and manage specialized equipment, laboratory space, analytical protocols, and appropriately trained personnel.

b. The FBI will provide funding for all work as stated in paragraph 5.

c. The FBI, or its designated agent, will retrieve, package, transport and deliver all unknown materials intended for assessment or analysis by FDA-FCC, specifically. The FBI will additionally provide documentation of all field collection, processing and screening efforts associated with the materials presented to FDA-FCC for examination. The evidence or analyzed materials will be returned to the FBI for disposition, or disposed of at the cost of the FBI. If required, FDA-FCC will store or dispose of evidence or analyzed material at the direction of the FBI. Any extra expense incurred for storage and disposal will be paid by the FBI.

d. With the approval of the FCC Director, the FDA-FCC will provide analysis of FBI samples.

e. With the approval of the FCC Director, FDA-FCC will provide expert technical advice and counsel as appropriate regarding subjects of mutual interest, as well as analytical characterization and/or forensic examination of submitted specimens, along with eventual courtroom testimony if required. Additionally, calling upon the resources of FDA-FCC as a whole, FDA-FCC will organize and coordinate training courses for Bureau personnel in particular areas upon request by the Chemical Biological Sciences Unit (CBSU) or the Hazardous Materials Response Unit (HMRU).

f. Possible Work Space Collocation and Collaborative Work: Consistent with personnel security requirements and good scientific practice, the parties may seek opportunities for project-specific collocation of personnel assets for professional development and training.

g. Field Exercises and Training: Whenever feasible, and consistent with the security requirements, the parties will seek opportunities for mutually beneficial technology transfers and training.

h. All work performed by FDA-FCC shall meet or exceed the quality assurance standards associated with the Bureau laboratory's accreditation.

i. FDA-FCC will immediately notify the FBI if any work being undertaken for the Bureau at FDA-FCC is negatively impacted by other work on-going at FDA-FCC for other customers or programs.

j. Reporting of the status, preliminary results, and/or results of the examination of FBI samples will be exclusively to the Bureau. Only those FDA-FCC staff members having a need to know the details of the

examinations conducted will be privy to same.

k. Inventions and Licensing: Activities conducted to carry out this MOA 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 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. Inventions resulting from joint research and development by both FDA-FCC and FBI employees shall be handled as jointly agreed to at the time of the disclosure.

4. BACKGROUND.

a. The FBI Laboratory's CBSU has the mission to conduct and/or direct the forensic examination of hazardous chemical, biological, and radiological/nuclear materials, and all related evidence. The FBI Laboratory traditionally has relied upon the assistance provided by the Department of Defense (DoD) and the Department of Energy (DoE) when responding to cases in which Weapons of Mass Destruction (WMD) are implicated. This MOA expands the scope of scientific resources within the U.S. Government (USG) that will be available to respond to acts of terrorism involving hazardous chemicals.

b. The FDA's Forensic Chemistry Center is charged with developing and maintaining state-of-the-art expertise in forensic analysis in support of FDA's mission to protect public health and safeguard the Nation's food and drug supply. This includes the development and implementation of new tools and analytical techniques to detect, identify, and fingerprint toxic chemicals in foods and drugs. The FCC is responsible for providing rapid response and specialized analytical services for activities related to product tampering, chemical terrorism, and counterfeit products. The FCC provides the analytical support and scientific expertise for FDA's Office of Criminal Investigations and upon request provides assistance to other Federal, State and Local agencies. The FCC is staffed with scientists whose training, background, and experience make them uniquely qualified to deal with foods and drugs contaminated with toxic chemicals.

5. FUNDING AND REIMBURSEMENT:

This Agreement is neither an obligation nor a commitment of funds, nor is it basis for a transfer of funds, but rather it is a statement of understanding between the parties. Expenditures by each party are subject to the parties' budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies. Funds provided by the FBI shall be considered obligated upon FDA-FCC acceptance of the funding authorization. Established FDA-FCC accounting procedures will be used for recording costs.

a. The FBI will fund FDA-FCC on an annual basis for recurring services under this agreement, including but not limited to: training deployments, FBI annual training at FDA-FCC, exercises, specialized training, analytical support and sample analysis. Additional work (within the scope, but in addition to that listed above, such as additional unforeseen analytical support and sample analysis) will be coordinated with FDA-FCC and will be funded on a reimbursable basis.

All funding documents must be provided to FDA-FCC in advance of initiation of work, and should be addressed to:

Donna J. Riley
Administrative Officer
U.S.FDA
Forensic Chemistry Center
6751 Steger Dr.
Cincinnati, Ohio 45237

b. The use of facilities and equipment and required facility upgrades (specifically the FBI's requirement for a facility upgrade to handle unknown samples) will be negotiated separately. The FBI will provide funding in advance of any action by FDA-FCC.

c. FDA-FCC will bill the FBI on a monthly basis for longer-term projects or per submission on shorter-term projects for all work performed. FDA-FCC will provide special reports, in a format designated by the FBI, on a quarterly basis for longer-term projects and per submission on shorter-term projects.

It is expected that the FBI's contracting Officer will send to the FDA-FCC a U.S. Department of Justice Reimbursement Agreement (Form DOJ-216) for reimbursement. A Reimbursement Agreement, DOJ-216, with funding will be issued for every task that is agreed to by the parties.

The FDA-FCC will sign and return the DOJ-216 as acceptance and will send a copy to the FBI's Contracting Officer. The FDA-FCC then will be able to submit charges to the Treasury in accordance with the U.S. Treasury's automated IntraBGovernmental Payment and Collection System (IPAC). Failure to provide this information on any IPAC billing will result in the IMMEDIATE charge back of the funds taken. Per the Business Rules for Intragovernmental Transactions issued by OMB on 10/04/02, the FDA-FCC will also include all other "Data Elements for Intragovernmental Bills" (e.g., selling agency's DUNS number) on each IPAC transaction. The FDA-FCC will provide reports to the FBI Contracting Officer, coinciding with each IPAC submitted, that will detail the items and/or services provided during the time period covered by the IPAC.

6. GUIDELINES, PROCEDURES, AND RESPONSIBILITIES.

a. A request for activation/deployment of appropriately trained FDA-FCC personnel to support CBSU for operational response to Domestic Terrorism or Special Event Security Protection, will originate from the Chief of the CBSU, and will be directed to the FDA-FCC Director for approval.

b. The FBI, or its designated agent, will retrieve, package, transport and deliver all unknown designated material to FDA-FCC. [SEE ABOVE]

c. FDA-FCC will identify and maintain a roster of technical experts for the purpose of providing expert opinions, technical assessments, and testimony as required, for missions under this MOA.

With the approval of the FCC Director these technical experts will be deployed CONUS subject to terms in separate operations plan (TBD).

d. All requests for FDA-FCC support for out of the continental united states (OCONUS) deployment will be made through the FDA-FCC Director FDA-FCC personnel traveling OCONUS under this MOA will be at all times identified as civilian personnel attached to the FBI deployment team.

7. POTENTIAL PERSONNEL ASSIGNMENTS.

a. FDA-FCC will provide certification to the FBI that each person nominated for a potential assignment (NTE one year) to the FBI Laboratory has a current SECRET clearance and the date of the latest background investigation. If higher clearances are required for specific assignments taken on behalf of the FBI than currently held by candidates, all costs associated with conducting or updating a candidate's background investigation will be borne by the FBI. Candidates with existing higher clearances may also be considered.

b. FDA-FCC will ensure that FDA personnel temporarily assigned to the FBI Laboratory, if any, are advised that throughout the period of an individual's assignment, he remains an FDA-FCC employee for all purposes during the period of this temporary assignment, including such matters as compensation, retirement, disability, and health benefits. For those employees during this period, the FBI will perform the timekeeping function and provide performance appraisal input. Additionally, any compensatory time earned during this assignment will be taken during the same assignment period. FDA-FCC will further ensure that their personnel are advised that they remain individually responsible for their personal insurance programs and that no insurance benefits are payable to them or their beneficiaries by the FBI.

c. To preclude inappropriate disclosure of information, each person temporarily assigned to the FBI under the terms of this MOA may be required to sign a General Nondisclosure Agreement and a Classified Information Nondisclosure Agreement (SF-312), as well as the new FBI form FD-868 (Non-disclosure Agreement for Task Force members/contractors).

d. Information generated for the FBI by FDA-FCC and by the FBI should be considered Law Enforcement Sensitive and exempt from the Freedom of Information Act.

8. CHANGES, REVIEWS, AND REVISIONS:

a. Cyclical reviews:

(1) This agreement will be reviewed upon the first anniversary of its effective date to determine if changes or revisions are required. This review will be initiated by the FBI within 90 days of the anniversary date. Revisions require bilateral agreement.

(2) After the first anniversary review, this agreement will be reviewed every three years. These reviews will be initiated by the

FBI within 90 days of the anniversary date. Revisions require bilateral agreement.

b. Out-of-cycle review: This agreement may be reviewed any time changes in mission or resources of the parties may adversely impact performance of this agreement. These reviews may be initiated by either party as required. Revisions may be suggested by either of the parties during any of the review processes, or at any time that a revision is necessary. Revisions require bilateral agreement.

c. All parties to this MOA shall not release information derived from the FBI to a third party without approval of the FBI. Reports of analysis released to the FBI by FDA-FCC can be used by the FBI for official use; however, in no case will the FBI attribute results to FDA-FCC without specific authorization of FDA-FCC. FDA-FCC technical reports, not paid for by the FBI, that are released to the FBI for information will be treated by the FBI in accordance with FDA-FCC rules for classification and distribution.

9. ADMINISTRATION.

The Designated FDA-FCC representative, and the Chief of the Scientific Analysis Section (SAS), FBI, will appoint staff elements to be responsible for implementation and administration of this agreement.

a. For the FDA-FCC, this MOA will be implemented and administered by the FCC Director. The point of contact (POC) for the FDA-FCC will be:

Fred Fricke
Director
Food & Drug Administration
Forensic Chemistry Center
6751 Steger Dr.
Cincinnati, Ohio 45237
(513)679-2700

b. For the FBI, this MOA will be implemented and administered by the CBSU. POC for the FBI will be:

Supervisory Special Agent David L. Wilson
Unit Chief, CBSU
FBI Laboratory
Quantico, VA
(703) 632-7766

c. For the FBI, the Finance Division POC for this MOA will be:

Mr. Ron Chiodi
Unit Chief, Construction and General Contracts Unit
(202) 324-0560

d. For FDA-FCC, the financial POC for this MOA will be:

Donna J. Riley
Administrative Officer
Forensic Chemistry Center

Each federal party agrees to notify the other federal party of any administrative claim arising out of an activity conducted pursuant to this MOU.

Nothing in this section prevents any party from conducting an independent administrative review of the incident giving rise to the claim; however, final disposition of the claim will be handled as provided in this Paragraph. Nothing in this section should be construed as supplanting any applicable statute, rule or regulation.

11. RESOLUTION OF CONFLICTS.

Nothing in this MOA shall take precedence or negate in any way the policy, directives, and procedures of the respective signatory agencies. Conflicts between this document and any other agency guidance shall be referred to the respective POC for resolution. If resolution cannot be satisfactorily achieved at this level, the responsible POCs shall forward the problem to the signatories of this MOA through their respective channels.

12. EFFECTIVE DATE TERM AND TERMINATION.

a. This MOA will have a term of 3 years, which can be extended for 3 years with bilateral agreement.

b. If termination of the MOA is desired by one agency, the termination agency shall notify the other agency through official channels, in writing, at the earliest possible time, but no later than 90 days prior to the desired termination date. The disposition of work in process, if any, at the time of the termination notification, shall be handled on a bilateral basis. In the event of termination, the requesting agency shall be liable for any costs associated with the termination.

c. This MOA shall become effective on the latest date of approval and signature by FDA-FCC and the Deputy Assistant Director, FBI Laboratory. It shall remain in effect until completion or specifically canceled or suspended by either agency.

APPROVAL PAGE FOLLOW

13. APPROVALS:

Dwight E. Adams, PhD.
Director, FBI Laboratory

Date: 11/3/04

Anthony J. Baumann
Chief Contracting Officer
FBI Finance Division

Date: 12/22/04

John M. Taylor
Associate Commissioner for
Regulatory Affairs
Food and Drug Administration

Date: 11.3.04

[FR Doc. 05–19339 Filed 9–27–05; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–3000]

Memorandum of Understanding Between the Food and Drug Administration and the National Library of Medicine

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 the Food and Drug Administration and the National Library of Medicine (NLM). The purpose of this MOU is to assign responsibilities to FDA's Center for Drug Evaluation and Research (CDER) and NLM for the distribution of product labeling.

DATES: The agreement became effective July 6, 2005, and supplements the agreement signed and dated November 21, 2001, and December 3, 2001, by NLM and CDER representatives, respectively.

FOR FURTHER INFORMATION CONTACT:

For FDA: Lisa Stockbridge, Food and Drug Administration (HFD–140), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7761; or Catherine Miller, Food and Drug Administration (HFD–140), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7772.

For NLM: Simon Liu, Bldg. 38A, rm. 2N221, 8600 Rockville Pike, Bethesda, MD 20894, 301–402–1698; or Stuart Nelson, Bldg. 38A, rm. B2E17, 8600 Rockville Pike, Bethesda, MD 20894, 301–496–1495.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S