The goal of Team Biologics is to ensure the quality and safety of biological products and quickly resolve inconsistencies and bring products into compliance. It is designed to promote uniformity between CBER and the field and among FDA field components associated with inspections, policy implementation, and current good manufacturing practice interpretation.

In April 1998, the responsibility for inspecting manufacturers of licensed in vitro diagnostics was transferred to Team Biologics investigators. The purpose of this workshop is to provide an overview of the Team Biologics concept to this segment of regulated industry, share the agency's experience with Team Biologics' inspections of manufacturers of licensed in vitro diagnostics to date, and provide manufacturers with an overview of FDA's expectations under this program.

The agenda and any other relevant information will be available electronically via the Internet at ''http://www.fda.gov/cber/scireg.htm''.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page. FDA will videotape the workshop and copies of the tapes will also be made available through the Freedom of Information Office.

Dated: June 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–17878 Filed 7–6–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–96–6000]

Memorandum of Understanding Between the Food and Drug Administration and the Defense Alliance for Advanced Medical Terminology

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 Defense Alliance for Advanced Medical Terminology (DAAMT). The purpose of the MOU is to enable government agencies to exchange information and jointly pursue research endeavors related to medical device safety and effectiveness.

DATES: The agreement became effective October 17, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3314, ext. 32.

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

Dated: June 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160–01–F

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
DEFENSE ALLIANCE FOR ADVANCED MEDICAL TECHNOLOGY
AND THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
September 1996

I. Purpose: A collaborative arrangement will be established between the Food and Drug Administration's Center for Devices and Radiological Health (FDA) and the Defense Alliance for Advanced Medical Technology (DAAMT). As the Department of Defense and other Government agencies move toward dual use and application of emerging technologies, especially in the area of applying these technologies to the development of new medical devices, improved cooperation, coordination and communication between the agencies sponsoring research and the FDA is in the national interest. This agreement will enable engineers, physicians and scientists from each organization to exchange information and jointly pursue research endeavors related to medical device safety and effectiveness.

II. Background: Over the past century, a vast array of technologies and technology support infrastructure has been developed for the national security requirements of the United States. Most of these resources reside under either the Department of Defense or the Department of Energy and are part of the science and technology base within the national laboratory structure. These resources have been directed primarily toward developing conventional and nuclear weapons systems used in defense.

With the recent changes in policy, priorities and alignments occasioned by the dissolution of the Soviet Union and the changing face of world political/social/economic realities, goals and resource utilization within the U.S. Government have been reevaluated, especially in the defense-related agencies. As a result, new priorities in technological development have emerged. Chief among these is the concept of dual-use technologies. Dual-use technology is basically the application of technologies to fields outside the initial field developing the technology. Increasing emphasis has been placed upon dual use by the current administration. As a result, the defense technology base is having to adapt to new paradigms in the area of technology development and cross-agency cooperation. Adding to the emphasis on dual use is the necessity for maintaining a viable technology base that can still meet the needs of the national defense. Meaningful dual-use technology guarantees a broader application base for the technology, while in no way detracting from the primary mission or capability of the laboratory performing the research. These highly desirable attributes are beginning to foster a wave of innovative thinking on multiple applications for defense technologies.

One of the most attractive and beneficial areas in which dual-use technology can be applied is the field of medical technology. Many of the technologies that have been

developed for defense applications are directly applicable to the medical field. This is not surprising given the striking similarities that can be found between the medical and the defense fields. For example, the concepts of target, target signature, identification of friend or foe, all have close analogs in the medical field (tissue identification, tissue biopsy, determination of benign versus malignant tissue). Further, not just technologies, but methodologies developed for use in the defense fields can also be applied to medical programs (test and evaluation planning, problem solving, and technology strategies to name a few). Unfortunately, there has been limited communication between the medical and defense technology communities. There are a variety of reasons for this, not the least of which are differences in culture and training between the two communities. Nonetheless, there still remain significant ways in which these two communities can work together for the benefit of both, as well as society.

Toward this end, the Defense Alliance for Advanced Medical Technology (DAAMT) was organized to provide a basis and framework to:

› break down the barriers that impede communication between the two communities.

› generate and promote innovative concepts and applications of defense technologies to the medical field and vice versa.

› identify and pursue resources and support for these applications and concepts.

› develop, improve, and enable the transition of these technologies and concepts to the Government and private sector to promote current national goals of improved health care and national defense.

The DAAMT was established by a Memorandum of Understanding between the USAF Wright Laboratory and the Walter Reed Army Institute of Research in October 1994 for an Alliance for the Cooperate Pursuit and Development of Defense Technologies for Medical Applications. Since its establishment, several other Federal agencies have joined DAAMT.

III. Substance of Agreement:

A. FDA's Center for Devices and Radiological Health will participate as a full member in the DAAMT without any transfer of funds from the FDA to the DAAMT. In place of the DAAMT membership fee, FDA will, through CDRH, contribute to the DAAMT goals and objectives by providing to DAAMT members, their contractors and other interested parties expert consultation regarding the regulatory process for medical devices and medical device development, testing and evaluation (both pre-clinical and clinical). The FDA will also provide consultation and training on regulatory requirements applicable to new devices. The FDA will also collaborate with DAAMT members by both providing access to FDA specialized laboratory

facilities and participating in projects utilizing DAAMT-member specialized laboratory facilities for specific projects of mutual interest. Specific projects will be planned and executed on a project-by-project basis by mutual agreement of the parties involved. Should specific projects require the transfer of funds, assignment of staff or permanent transfer of equipment, an appropriate Interagency Agreement will be developed for that purpose.

B. The DAAMT will include the FDA in its projects and endeavors to promote dual use of medical device technology and technology relevant to medical device development. DAAMT members will collaborate with FDA by providing access to their specialized laboratory facilities and participate in projects utilizing FDA's specialized laboratories. Specific projects will be planned and executed on a project-by-project basis by mutual agreement of the parties involved.

C. The Memorandum of Understanding between USAF Wright Laboratory and Walter Reed Army Institute of Research, Division of Surgery for an Alliance for the Cooperative Pursuit and Development of Defense Technologies for Medical Applications dated 4 October 1994 and the Addendum to that Memorandum of Understanding dated 10 February 1995 shall provide the basis for the organization and operation of the Defense Alliance for Advanced Medical Technology and the Food and Drug Administration's participation in the DAAMT.

IV. Name and Address of Participating Parties:

Defense Alliance for Advanced Medical Technology
Colonel William P. Wiesmann, Chair
Walter Reed Army Institute of Research
Division of Surgery, Building 40
14th and Dahlia Streets
Washington, DC 20307
TELEPHONE: (202) 782-3791

Center for Devices and Radiological Health
Food and Drug Administration, DHHS
9200 Corporate Boulevard
Rockville, Maryland 20850
TELEPHONE: (301) 443-4690

V. Liaison Officers:

For the Defense Alliance for Advanced Medical Technology:

William P. Wiesmann, M.D.
Colonel, USA, Medical Corps
Director, Division of Surgery, Walter Reed Army Institute of Research
Chair, Defense Alliance for Advanced Medical Technology
Division of Surgery, Building 40
14th and Dahlia Streets
Washington, DC 20307
TELEPHONE: (202) 782-3791

For the Food and Drug Administration:

Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science, Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard (HFZ-2)
Rockville, Maryland 20850
TELEPHONE: (301) 443-4690

FDA Technical Liaison:

Thomas B. Shope, Ph.D.
Acting Director, Division of Electronics and Computer Science (HFZ-140)
Office of Science and Technology
Center for Devices and Radiological Health, FDA
Rockville, Maryland 20857
TELEPHONE: (301) 443-3314, Extension 32

VI. Period of Agreement: This agreement becomes effective upon acceptance by both parties, and will continue in effect for a period of five (5) years from date of signature. It may be modified by mutual written consent or terminated by either party upon a 30-day advance written notice to the other party. During the last six (6) months of the agreement, it will be reviewed by both parties as to the need to continue the agreement.

VII. Funding of Project: No funding will be provided by the FDA to DAAMT as part of this agreement. FDA personnel and laboratories will collaborate with other members of the DAAMT on projects of mutual interest. Facilities and equipment of each party will be made available to the other in accordance with individual project plans and agreements.

VIII. Reporting Requirements: Reporting responsibility will be determined on a case-by-case basis based upon project requirements. Reports will be provided as necessary to all DAAMT members.

IX. Schedules and Milestones: Schedules and milestones for collaborative projects will be developed by mutual agreement for individual projects.

X. Disposition of Data: The project plan for each collaborative project will specify the disposition of data which may result from the project. Data collected by DAAMT members, including FDA, in the course of collective activities will be shared as described in the specific project plan. If the results of data collected in joint activities are published, both DAAMT and the FDA will be acknowledged. Data, whose disclosure by FDA is prohibited, will not be shared unless appropriate safeguards are established in the individual project plan.

XI. Sharing Data and Information: FDA and DAAMT recognize the need to protect trade secret, confidential commercial, financial, personal and medical information from disclosure. However, FDA and DAAMT believe that an exchange of data and information to the extent allowed by law is necessary to achieve the ends of this agreement. Therefore, to the extent allowed under 21 U.S.C. § 331(j), 21 U.S.C. § 360j(c), 42 U.S.C. § 353g(d), 42 U.S.C. § 263i(e), and 21 C.F.R. Part 20, FDA agrees to share data and information with DAAMT upon request.

XII. Disclosure of Data and Information in Response to Requests: If disclosure of data or information exchanged under this MOU is requested by a request under the Freedom of Information Act, a Congressional inquiry, or pursuant to other regulatory responsibilities, the agency that receives the request shall notify the agency that provided the information if they are not the same agency. The notified agency will be responsible for making any needed contact with the submitter of the protected information and will accept the responsibility for evaluating the submitter's comments prior to rendering the disclosure determination.

To preserve maximum control over actual disclosure of its own records, each agency shall retain legal authority and the commensurate responsibility over disclosure of those documents provided to the other agency.

XIII. Government Property/Facilities: Both parties will make available personnel and facilities as required by individual projects based on the mutually developed project plans.

APPROVED AND ACCEPTED for the Defense Alliance for Advanced Medical Technology

BY _____ 10/17/96
William P. Wiesmann, M.D. DATE
COL, USA, MC
Chair, Defense Alliance for Advanced Medical Technology

APPROVED AND ACCEPTED for the Food and Drug Administration

BY _____ 10/17/96
Elizabeth D. Jacobson, Ph.D. DATE
Deputy Director for Science
Center for Devices and Radiological Health
Food and Drug Administration

[FR Doc. 98–17859 Filed 7–6–98; 8:45 am]
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