Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 3 and 4, 1999, the Xenotransplantation Subcommittee will discuss the following public health issues concerning porcine xenotransplantation: (1) Update of scientific data concerning porcine endogenous retrovirus, (2) update of patient monitoring and screening data concerning patients who have received a porcine xenograft, (3) update on FDA xenotransplantation policy development, and (4) proposals for solid organ xenotransplantation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 27, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. to 9:15 a.m. and 5:30 p.m. to 6 p.m. on June 3, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 20, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 12, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–12519 Filed 5–13–99; 4:24 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA 225–99–4000]

Memorandum of Understanding Between the Food and Drug Administration and the U.S. Army Medical Research and Material Command

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 U.S. Army Medical Research and Material Command. The purpose of the MOU is to define responsibilities during the research, development, and pre-marketing acquisition of medical material for military applications.

DATES: The agreement became effective November 16, 1998.

FOR FURTHER INFORMATION CONTACT: Steven M. Solomon, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0386.

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 Registe**r, the agency is publishing notice of this MOU.

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160–01–F

225-99-4000

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
AND
THE FOOD AND DRUG ADMINISTRATION

SUBJECT: Quality Assurance Support for Medical Materiel Having Military Application

1. Purpose. This Memorandum of Understanding (MOU) formalizes the relationship and defines the responsibilities of the U.S. Army Medical Research and Materiel Command (USAMRMC) and the Food and Drug Administration (FDA) to each other during the research, development, and pre-marketing acquisition of medical materiel for military application.

2. Background. The USAMRMC mission of research, development, testing, and evaluation of medical materiel for military application, to include drugs, biological products, protective cosmetics, and medical devices, requires significant interface with contractors to assure a reliable, safe product. The FDA mission of regulation, inspection, and oversight to insure that quality products are provided presents a unique opportunity for the FDA to assist USAMRMC in developing quality medical materiel.

3. Scope. The MOU is limited to quality assurance support by the FDA for USAMRMC Advanced Development (6.4) and Engineering Development (6.5). Medical materiel, for the purpose of this MOU, includes drugs, biological products, protective cosmetics, and medical devices.

4. Responsibilities.

a. The U.S. Army Medical Research and Materiel Command will:

(1) Involve the FDA at the earliest practicable stages of materiel development.

(2) Provide the FDA with an annual five year projected milestone schedule of developmental items.

(3) Seek FDA advice regarding contractor suitability prior to awarding contracts for development of prototypes and pre-production products under consideration for Department of Defense (DOD) application.

(4) Seek FDA advice in the review of draft product specifications and other documents to help identify and resolve at the earliest possible time potential regulatory and/or quality assurance issues.

(5) Retain final authority in selection of contractors for materiel development contracts.

(6) Provide advance notice when naming FDA as the Government Accepting Authority for materiel under a USAMRMC contract.

b. The Food and Drug Administration will:

(1) Upon request, provide pre-award evaluations of prospective contractors for prototype development and preproduction product contracts.

(2) Upon request, provide review of draft product specifications and other documents.

(3) Upon request, act as the Government Accepting Authority for USAMRMC medical materiel contracts. This will include signatory authority for Materiel Inspection and Receiving Reports (DD Form 250). The FDA reserves the right to not act as the accepting authority when the FDA has not had the opportunity to provide a pre-award evaluation prior to award of the contract, or when USAMRMC's choice of contractor has been evaluated by FDA and found not acceptable.

(4) Use the applicable requirements of the Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder as the quality standard for determining contractor and product acceptability. Other requirements deemed essential, due to the military uniqueness of an acquisition, will be specified by USAMRMC.

(5) Determine the amount and nature of work it will perform to fulfill its responsibilities under this MOU.

5. Administration.

a. This agreement will become effective upon final signature and will remain in effect for six (6) years.

b. The agreement will be reviewed every two (2) years on the last signature anniversary date, to ensure adequacy and currency;

however, it may be amended by mutual consent at any time.

c. The agreement may be unilaterally terminated by providing the other party with 180 days written notice of intent.

d. Resources required to support this MOU, to include travel and per diem costs, will be provided by the performing party.

e. Points of contact.

(1) USAMRMC - Mailing Address: U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Ft. Detrick, MD 21702-5012. Telephone: 301-619-2165.

(2) FDA - Mailing Address: U.S. Food and Drug Administration, Medical Products Quality Assurance Staff (HFC-240) 12720 Twinbrook Parkway, Suite 400, Rockville, MD 20857. Telephone: 301-827-0390, ATTN: Director, Medical Products Quality Assurance Staff.

John Parker
Major General, MC
Commanding
U.S. Army Medical Research and Materiel Command

16 NOV 98
DATE

RONALD G. CHESEMORE
Associate Commissioner for Regulatory Affairs
Food and Drug Administration

OCT - 9 1998
DATE

[FR Doc. 99–12397 Filed 5–17–99; 8:45 am]
BILLING CODE 4160–01–C