

AMENDMENT A  
To  
MEMORANDUM OF UNDERSTANDING  
Between the  
DEPARTMENT OF DEFENSE  
And the  
FOOD AND DRUG ADMINISTRATION  
(225-74-1012)

This agreement is in regard to licensure of military blood banks.  
The section on liaison officers is changed to read:

III. Liaison Officers

- A. Director of Military Blood Program Office  
DASG/MEDB  
(Currently Colonel Hubert Wrenn)  
Pentagon, Room 2D533  
Washington, D.C. 20310  
Telephone: 697-0819
- B. Director, Division of Compliance  
Bureau of Biologics, HFB-600  
(Currently Mr. Sammie R. Young)  
Food and Drug Administration  
8800 Rockville Pike  
Bethesda, MD 20205  
Telephone: 443-5217

APPROVED AND ACCEPTED FOR THE  
DEPARTMENT OF DEFENSE

By John Beary MD  
Acting Asst. Sec of Defense  
Title (Health Affairs)

Date 9 October 1981

APPROVED AND ACCEPTED FOR THE  
FOOD AND DRUG ADMINISTRATION

By Joseph P. Hile  
Joseph P. Hile  
Title Associate Commissioner for  
Regulatory Affairs

Date SEP 24 1981



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 24 1981

Colonel Hubert Wrenn  
Director of Military Blood Program Office  
DASG/MEDB  
Pentagon, Room 2D533  
Washington, D.C. 20310

Dear Colonel Wrenn:

We enclose an amendment to the memorandum of understanding between the Department of Defense and the Food and Drug Administration regarding the licensure of military blood banks.

This amendment will identify the liaison officers by position rather than name, although the current person in each position is given in parenthesis. This eliminates the need for a formal amendment each time there is a personnel change in the liaison officers' positions.

If this amendment meets with your approval, please sign both copies and return them.

Sincerely yours,

A handwritten signature in cursive script, which appears to read "Joseph P. Hile", is written over the typed name.

Joseph P. Hile  
Associate Commissioner  
for Regulatory Affairs

Enclosure

MEMORANDUM OF UNDERSTANDING  
BETWEEN THE  
DEPARTMENT OF DEFENSE  
AND THE  
FOOD AND DRUG ADMINISTRATION

The Department of Defense (hereinafter called DOD) and the Food and Drug Administration of the Department of Health, Education, and Welfare (hereinafter called FDA) hereby jointly agree to the terms and conditions as described herein.

Purpose: To establish a uniform policy between the Department of Defense and the Food and Drug Administration relative to the voluntary licensure of military blood banks pursuant to Section 351 of the Public Health Service Act.

Background

Blood, blood components or derivatives, or analogous products applicable to the prevention, treatment, or cure of diseases or injuries of man (henceforth referred to as biological products) are potentially subject to the licensing provisions of Section 351 of the Public Health Service Act, which is enforced by the Bureau of Biologics of the Food and Drug Administration. These biological products are human "drugs" as that word is defined under the Federal Food, Drug, and Cosmetic Act, which is also enforced by the FDA. Biological products and the manufacture of such products are therefore subject to both Section 351 of the Public Health Service Act and the human drug provisions of the Federal Food, Drug, and Cosmetic Act.

The Department of Defense wishes to voluntarily avail itself of the licensing provisions of Section 351 of the Public Health Service Act, to enable the military to more freely and expeditiously exchange blood and blood components with civilian blood banks to more effectively utilize this vital national blood resource. The Food and Drug Administration, for its part, looks with favor upon the entrance and integration of certain aspects of the military blood system with that of the civilian system to move the nation's blood services complex more nearly towards one nationwide system with uniform standards of quality and safety.

Inasmuch as both the Food and Drug Administration and the Department of Defense recognize the unique nature and capabilities of the military blood banking system, and in recognition of their mutual recognition of the military need for flexibility to assure the common defense, a mechanism to implement the licensing provisions of Section 351 of the Public Health Service Act has been agreed upon which will adequately serve the public health goals of Section 351 without in any way compromising the military's capacity to respond effectively in meeting urgent military requirements.

## I. Substance of Agreement

The Food and Drug Administration and the Department of Defense agree that:

1. Upon application for FDA license, each military department volunteers to be licensed with respect to its military blood program.
2. Each military department will apply to the Food and Drug Administration for issue of a separate license. These licenses will be equivalent to those issued to civilian blood programs in accordance with Section 351 of the Public Health Service Act. Exceptions to the license not covered in this agreement will be coordinated by the military department concerned with the Food and Drug Administration.
3. Each military department will insure that its blood banking facilities will meet the standards prescribed and are operated in accordance with FDA blood banking regulations. Each military department on its own or in conjunction with other military departments, will provide for the inspection of its blood banks by qualified personnel to insure that the facilities are operated in accordance with FDA regulations. The inspections will use criteria equivalent to or exceeding those employed in the inspection of civilian blood banks.
4. FDA inspection of military blood banking facilities will be conducted as deemed necessary and will be coordinated with the licensee of each military department.
5. Discrepancies noted or deviations from the governing FDA regulations will be reported to the Surgeon General of the military service involved by the designated inspectors. Each Surgeon General shall be responsible for taking the corrective action necessary to insure compliance. Inspection reports will be available both to the Surgeons General and the FDA.
6. For national security, the Department of Defense must maintain a world-wide capability for medical care. The military departments during military operations, military and/or civilian emergencies may be required to deviate from the blood banking standards of the FDA. FDA will be made aware of the deviations from the FDA standards and their medical implications.

## II. Name and Address of Participating Agencies

- A. Department of Defense  
Washington, D. C. 20314
- B. Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20852

III. Liaison Officers

A. Hal G. Etter, COL, BSC, USAF  
 Director of Military Blood Program Office  
 Office of the Surgeon General  
 U. S. Army  
 Department of Defense  
 Washington, D. C. 20314  
 Telephone: (202) 693-5575

B. Mr. James O. Gesling  
 Associate Director  
 Bureau of Biologics, HFB-3  
 Food and Drug Administration  
 8800 Rockville Pike  
 Bethesda, Maryland 20014  
 Telephone: (301) 496-6807

IV. Period of Agreement

This agreement, when accepted by both agencies, covers an indefinite period of time, and may be modified by mutual consent of both parties or terminated by either party upon a thirty (30) day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE  
 DEPARTMENT OF DEFENSE

APPROVED AND ACCEPTED FOR THE  
 FOOD AND DRUG ADMINISTRATION

By *N. M. ...*

By *A. M. Schmidt*

Title Actg Asst Secretary of Defense  
 (Health and Environment)

Title Commissioner of Food & Drugs

Date 19 June 1974

Date 21 May 1974