

Inspection of Military Blood Establishments (6/18/92)

Date June 18, 1992

From Director, Division of Field Investigations (HFC-130)

Subject Inspection of Military Blood Establishments,
Revised instructions for Command Notification

To Investigations Branch Directors

Info: District Directors
Regional Food and Drug Directors

Mr. Chesemore's memorandum of May 6, 1992 gave instructions for the transfer of 30 licensed military blood banks to the field inventory. This memorandum modifies the military headquarters notification procedures and provides interim instructions for compliance procedures.

Districts should now notify the military of approaching inspections directly and do not need to go through CBER. Contacts for the three branches of the military, which operate licensed blood bank locations, are attached. The headquarters command of the respective military branch should be notified about two weeks before an inspection to allow a check for operations affecting the inspection such as war games. These military contacts will be included in the Contacts for Other Federal Agencies in Part VI of compliance program 7342.001, Inspection of Licensed and Unlicensed Blood Banks when it

When deviations from the regulations are encountered during the inspection of a military blood bank, issue the FDA 483 to the most responsible individual on site. Send a copy of the FDA 483 to the Responsible Head of that military establishment and to the Office of Compliance, Division of Inspections and Surveillance, Biological Product Inspection Branch (HFB-122.) An example of a post inspection letter for a military blood bank is attached.

Military blood banks must meet the same safety and quality standards as civilian blood banks. If deviations indicate immediate action is needed or if reinspection demonstrates adequate corrective actions have not been taken, notify the Division of Case Management (HFB-110) as soon as possible to determine if the violations warrant issuance of a Warning Letter or other action. Please inform the Division of Field Investigations (HFC-130) of such cases too.

Please continue to assure experienced, well-qualified investigators with significant blood banking experience are assigned to these inspections.

Robert C. Fish

LOCATION	ESTABLISHMENT	LICENSE NO.
Wright Peterson, OH	USAF Medical Center	610-003
Orlando, FL	Naval Hospital	635-007
Jacksonville, FL	Naval Hospital	635-017
Keesler AFB, MS	USAF Medical Center	610-005
Ft. Polk, LA	US Army Hospital	611-022
Ft. Knox, KY	US Army Hospital	611-008
Millington, TN	Naval Hospital	635-008
Travis AFB, CA	USAF Medical Center	610-002
San Francisco, CA	Letterman Army Med Ctr	611-009
Ft. Ord, CA	Armed Services BB	611-012
Camp Pendleton, CA	Naval Hospital	635-003
Long Beach, CA	Naval Hospital	635-005
San Diego, CA	Naval Hospital	635-001
Charleston, SC	Naval Hospital	635-016
Beaufort, SC	Naval Hospital	635-012
Ft. Carson, CO	US Army Hospital	611-015
Aurora, CO	US Army Hospital	611-003
Colorado Springs, CO	USAF (Academy) Hospital	610-009
Ft. Leonard Wood, MO	US Army Hospital	611-014
Ft. Riley, KS	US Army Hospital	611-016
Portsmouth, VA	Naval Hospital	635-002
Lackland AFB, TX	USAF Medical Center	610-001
Ft. Sam Houston, TX	US Army Hospital	611-001
Newport, RI	Naval Hospital	635-011
Ft. Dix, NJ	US Army Hospital	611-011
Philadelphia, PA	Naval Hospital	635-015
Honolulu, HI	US Army Hospital	611-006
Minot AFB, ND	USAF Medical Center	610-010
Ft. McClellan, AL	US Army Hospital	611-020
Tacoma, WA	US Army Hospital	611-007

COMPLIANCE PROGRAM 7342.001

CONTACTS FOR OTHER FEDERAL AGENCIES

Veterans Administration Hospitals

E.M. Travers, M.D.
 Director of Pathology Services, Symbol #111F
 Department of Medicine and Surgery
 Veterans Administration
 810 Vermont Avenue, N.W.
 Washington, DC 20420
 8-535-7075 Comm: 202-535-7075

Indian Health Service Hospitals

Linda Meacher
 Division of Research Coordination

Indian Health Service
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
8-443-4680

Military contacts (Districts should notify military contacts directly, at least 30 days in advance of the inspection.)

Lt. Colonel Suellyn Novak, Air Force, 202-767-5054
Lt. Colonel Robert Pick, Army, 703-756-0153 or
Lt. Colonel Richard Brown, Army, 703-756-4611
Commander Bruce Rutherford, Navy, 202-653-1086

Responsible Heads for Military

Lt. General Alexander M. Sloan
Department of the Air Force
HQ USAF-SGHR
Bolling AFB, DC 20332

Vice Admiral D.F. Hagan
Department of the Navy
Bureau of Medicine and Surgery, MED-OO
Washington, DC 20372-5120

Lt. Gen. Frank F. Ledford, Jr.
Department of the Army
5 Skyline Place, Attn: HQDA (SGPS-CP-L)
5109 Leesburg Pike
Falls Church, VA 22401-3258

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH PROGRAM CONTACTS

General Compliance Matters, Imports, Exports, Inspections,
Samples, Complaints, Product Defects, Errors and Accidents,
Fatalities, Viral Marker Testing, Computer Issues, GMP Guidance:

Office of Compliance, Division of Inspections and Surveillance,
HFB-120
Boyd Fogle, Jr., Director.
Telephone: FTS 295-8191 or 301-295-8191

Contact Persons within Biological Product Inspections Branch,
HFB-122 (FTS 295-8191 or 301-295-8191), for questions pertaining
to:

Margaret A. Tart, Chief
Viral Marker Testing: Cathy Conn or Sharon O'Callaghan
Fatalities: Mary Ann Tourault
Errors & Accidents Sharon O'Callaghan or Janet Ishimoto

Contact persons within Surveillance and Policy Branch, HFB-124
(FTS 295-8191 or 301-295-8191), for questions pertaining to:

Fred Blumenschein, Chief
Imports & Exports: Fred Rangel or Kim Migliore
Product Defect Reports
& Consumer Complaints: Jerome Davis
Compliance Programs
& CPG's: Fred Rangel
Computer Issues: Alice Godziemski

Case Guidance, Warning Letters, Legal Actions, License
Revocations, .
Suspension of Operations Under License, Recalls

Office of Compliance, Division of Case Management, HFB-110
Steven Masiello, Director
Telephone: FTS 295-8185 or 301-295-8185

Case Guidance Branch, HFB-114
Emilie Sanborn, Chief

Recalls and Administrative Actions Branch, HFB-112
Chief - vacant

Consumer Affairs Representative

Division of Congressional and Public Affairs, HFB-140
Congressional, Consumer and International Affairs Branch
Chief - vacant
Telephone: FTS 295-8228 or 301-295-8228

Licensing and Labeling of Products, Variances; Approvals for
Changes in Personnel, Location, Off-site Storage, Manufacturing
Methods, Registration, etc.

Division of Product Certification, HFB-240
Blood Products and Diagnostics Branch
Mary Gustafson, Chief
Telephone: FTS 295-8428 or 301-295-8428

Contact persons within DPC for questions pertaining to:

Blood bank licensing issues: Linda Amendt or Karan Repsher
Registration: Barbara Coates

SOP's, Donor Medical History Forms, AIDS Educational Materials,
Consent Forms, and Technical Information Relating to Blood
Products

Office of Biologics Research
Division of Transfusion-Science
Ann Hoppe, Acting Director

Laboratory of Blood Bank Practices, HFB-940
Telephone: 301-227-6487 or FTS 394-6487

ORA CONTACT

ORA/ORO/DFI
Investigations Operations Branch, HFC-132
Telephone: FTS 443-3340 or 301-443-3340

Compliance Program 7342.001 Attachment I

Rear Admiral Robert Higgins (NAME AND ADDRESS OF RESPONSIBLE
HEAD)
Department of the Navy
Bureau of Medicine and Surgery
Washington, D.C. 20372-5120

Dear Admiral Higgins: :

An inspection of the U.S. Naval Hospital located at TOWN, STATE
on DATE revealed deviations from Title 21, Code of Federal
Regulations. At the conclusion of the inspection, the inspector
discussed these deviations with NAME & RANK/TITLE OF PERSON
RECEIVING THE FDA-483 and OTHERS PRESENT AT THE CLOSEOUT
provided them with a written list of these observations. A copy
of this document, Form FDA-483, is enclosed.

Please advise us, in writing, of your actions to correct the
deviations noted, within 30 days of receipt of this letter, in
sufficient detail to permit us to determine compliance with the
regulatory standards.

Sincerely yours,

DISTRICT DIRECTOR

CC: HFB-120

Attachment

DATE: June 12, 1992

FROM: Chief, Surveillance and Policy Branch (HFB-124)/
Division of Inspections and Surveillance/Office of
Compliance/
Center for Biologics Evaluation and Research

SUBJECT: Notification of Reported Change - For Your Information
Type of Change: Signature Representative, US License 0610

TO: Director, Investigations Branch (SAN-DO/HFR-PA150)

1. Due to the pending retirement of Colonel Albert B. Briccetti, the new signature representative for Lieutenant General Alexander M. Sloan, Surgeon General; pursuant to the Code of Federal Regulations, Title 21, part 601.12(a) is:

Peter F. Hoffman, Colonel, USAF, MC
Associate Director, Medical Plans and Resources
Office of the Surgeon General

2. Questions and correspondence may be directed to the Surgeon General through the blood program office, HQ USAF/SGHR, Attention: Lt Col Suellyn W. Novak, Bolling AFB DC 20332-6188, (202) 767-5054.

Frederick U. Blumenschein

DEPARTMENT OF THE AIR FORCE
HEADQUARTER UNITED STATES AIR FORCE
BOLLING AFB DC 20332-6188

February 25, 1992

SUBJECT: Change In tho Signature Representative, US License 610

TO: Director, Division of Product Certification
Center for Biologics Evaluation & Research/HFB-240
Food and Drug Administration
8800 Rockville Pike
Bethesda MD 20892

1. Due to the pending retirement of Colonel Albert B. Briccetti, my new signature representative pursuant to the Code of Federal Regulations, Title 21, part 601.12(a) is:

Peter F. Hoffman, Colonel, USAF, MC
Associate Director, Medical Plans and Resources
Office of the Surgeon General

2. Questions or correspondence may be directed to me through our blood program office, HQ USAF/SGHR, Attention: Lt Col Suellyn W. Novak, Bolling AFB DC 20332-6188, (202) 767-5054.

ALEXANDER M. SLOAN
Lieutenant General, USAF, MC
Surgeon General

The information submitted herewith has

been noted and filed with your license
application.
This notification constitutes official
acknowledgment

Linda Amendt 3/3/92
Div. Prod. Certification
Center for Biologics Evaluation and Research