QUALITY ASSURANCE RECALL/ALERT

Recall No.: DPSC 970147
CDCS No.: M97336048

FROM: DPSC-MSCBA PRM

TO: USAMMA NAVMEDLOGCOM, AFMLO, for distribution to: PHS, VAMC, and DMSB.

1. REFERENCES:
   A. ITEM:
   B. Part No(s): Lot No(s):
   C. Recalling Firm/Manufacturer:
   D. FDA Project No.

2. The enclosed Product Recall is provided for your information and appropriate action.

3. The following additional remarks are provided:
   A. REASON:
   B. DISPOSITION:
   C. P.O.C.:

4. 

5. DPSC point of contact is James A Johanson, phone DSN 444-7224, commercial (215) 737-7224. FAX extension is 2058, e-mail is jjohanson@dpsc.dla.mil.

cc: Company file
DISC Q2 RISK OF BLOOD BORNE DISEASE TRANSMISSION
CAUSE OT UNILATERAL ACTION BY MANUFACTURER.
DISP OT DO NOT USE UNTIL EVALUATION AND RESOLUTION OF ISSUES.
CORR NO NO ACTION REQUIRED
VIA UPS NEXT DAY AIR
Dr. Edward Martin
Acting Assistant Secretary of Defense for Health Affairs
United States Department of Defense
Room 3E346.1200 Defense Pentagon
Washington, D.C. 20301-1200

Dear Dr. Martin:

We are the manufacturer and distributor of a multiple dose injector designed by the Armed Services called the Ped-o-Jet. Our Company has sold a number of units of this product to the Armed Services of the United States. We are writing this letter to you in your capacity as Acting Assistant Secretary of Defense for Health Affairs.

In 1996 and again in March 1997, the Center for Disease Control and the World Health Organization held a meeting to discuss the topic of mass inoculation. Many organizations and nations had representatives at these meetings. The Armed Services of the United States and FDA. attended these meetings, as well as a Colonel Bancroft and other representatives of the Armed Services. In 1997, this group participated and was responsible for the development of a report entitled "Steering Group on the Development of Jet Injection for Immunization". One of the topics in the report discussed the potential risk of blood borne disease transmission where a multiple use jet injector is used.

In its very long history the Ped-o-Jet has never had a reported case of cross contamination and quite frankly, has enjoyed and still has an exemplary record. However, as a result of the findings set forth in the report, we will discontinue producing and servicing the Ped-o-Jet at this time.

We believe that further studies would be required to ensure that the Ped-o-Jet is a safe method for administering mass injections. Until such studies conclude than no risk is present for blood borne disease transmission, we strongly urge the Armed Forces to discontinue use of the product.
Dr. Edward Martin  
November 20, 1997  
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We expect that you will communicate the contents of this letter and our recommendation to all divisions of the Armed Services currently in possession of a Ped-o-Jet.

I have enclosed a list of all of the Armed Services locations where Ped-o-Jets have been sold during the last approximately four years since we purchased the assets of Ped-o-Jet.

If you have any questions about the contents of this letter, please do not hesitate to contact us toll free at (800) 333-3131.

Very truly yours,  
PED-O-JET INTERNATIONAL  
Fred I Robinson  
Chairman and Chief Executive Officer

Naval Hospital, 1 Pinckney Blvd., Beaufort, SC 29902
59th Medical Wing, 2200 Berquist Drive, Lackland AFB, TX 78236
Naval Medical Center, Bldg. #250, Portsmouth, VA 23708
Naval Medical Center, 34700 Bob Wilson Drive, San Diego, CA 92134
Naval Station - Guantanamo Bay, Jacksonville, FL 32212
U.S. Army Health Clinic, Fort McPherson, GA 30330
Naval Hospital, 6000 West Highway 98, Pensacola, FL 32512
U.S. Coast Guard, 01 Munro Avenue, Cape May, NJ 08204
U.S. Army Medical Department, Ft, Leonard Wood, MO 65473
USNS 'Comfort", 4209 New Gate Avenue, Pier 11, Baltimore, MD 21224
Naval Hospital, Cherry Point, NC 28533
Medical Center, 204 Wagner Drive, Kelly AFB, TX 78241
Defense Distribution Department, Susquehanna, Mechanicsburg, PA 17055
USCG Academy Clinic, Medical Administration, 15 Mohegan Avenue, New London, CT 06420
Moncrief Army Hospital, Fort Jackson, SC 29207

United States Marine Corps, Bldg, 669, Boulevard DeFrance, Parris Island, SC 29905

Naval Hospital, Camp Pendleton, CA 92055

Naval Hospital, 3001 -A 6" Street, Great Lakes, IL 60088-5230
PED-O-JET PARTS ONLY

U. S. Marine Corps, Material Management Department, Building 2201-A
Quantico, VA 22134

Noble Army Hospital Clinic, Building 292, Material Branch, Fort McClellan, AL
36205

DFAS - Columbus, DFAS - CO - SEM, P.O. Box 182317, Columbus, OH 43218
For ultimate consignee:
B-TW-MPR, Army Medical Depot, Taiwan

Medical Supply Office, Building #9222, Fort Benning, GA 31905

Naval Medical Clinic, 881 USS James Madison Avenue, Building 1028,
Kings Bay, GA 31547

DFAS - Columbus Center DFAS - CO - SEM, P.O. Box 182317, Columbus, OH 43218

Materials Management, Naval Hospital, 10651 "E" Street, Corpus Christi, TX 78419

MEDICAL Supply Officer/FM2805, 95 MDSS/SGSL, 32 Hospital Road, Building 5518
Edwards AFB, CA 93524

Contract Officer, Naval Hospital, 6500 Navy Road, Millington, TN 38054

Naval Environmental & Preventive, Medicine - Unit 2, 1887 Powhatan Street,
Norfolk, VA 23511

Naval Hospital, Receiving Officer - Building 1145, Twentynine Palms, CA 92278

For ultimate consignee: USS Fort McHenry - LSD 43