U.S. Department
of Transportation

**Research and
Special Programs
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

MAY 30 1997

DOT-E 11572

EXPIRATION DATE: March 1, 1999

(FOR RENEWAL, SEE 49 CFR SECTION 107.109)

1. GRANTEE: North American Biologicals, Inc. (NABI)
   Miami, Florida

2. PURPOSE AND LIMITATION: This exemption authorizes the transportation in commerce of frozen human source blood plasma that contains an infectious substance in special packaging by contract carrier from NABI donor (collection) centers located in cities throughout the United States to the NABI central processing facility located in Miami, Florida. This exemption provides no relief from any regulation other than as specifically stated herein.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR 173.196(b) and 173.196(f).

5. BASIS: This exemption is based on the application of NABI, dated August 25, 1995 and supplemental information, dated October 5, 1995 and October 17, 1995, submitted in accordance with 49 CFR 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous materials description -- proper shipping name	Hazard Class/ Division	Identi- fication Number	Packing Group
Infectious substances, affecting humans*	6.2	UN2814	(N.A.)

* Frozen plasma containing any of the following infectious substances may be transported under this exemption: (1) human immunodeficiency virus (HIV), (2) hepatitis B virus (HBV), and/or hepatitis C virus (HCV).

7. PACKAGING AND SAFETY CONTROL MEASURES:

a. PACKAGING - Materials listed in paragraph 6 above must be packed in authorized packagings and components, as follows:

(1) Inner packagings. Inner packagings must be as specified in 49 CFR 173.196(a)(1). Inner packagings may contain not more than 1000 ml (1.057 quart) of plasma.

(2) Outer packaging. Outer packaging must be a single wall (double-faced) corrugated fiberboard box with single wall corrugated dividers (partitions) that form multiple, snug fitting cells. Dividers must be removable to accommodate inner packagings. The bursting strength of the box may not be less than 1379 kPa (200 psi). The edge crush strength of the box may not be less than 5.6 kN/m (32 lbs/in). The gross weight limit of the box may not be less than 29.5 kg (65 lbs). More than one inner packagings may be packed in an outer packaging. Inner packagings must be securely cushioned in the outer packaging with non-reactive, absorbent material. Outer packaging may contain not more than 4000 ml (1.057 gal) of plasma. Ice (wet or dry, as necessary), appropriately packaged, may be packed in the outer packaging to preserve the plasma. The gross weight of the package may not exceed 6.8 kg (15 lb).

b. TESTING - Samples of the packaging, prepared as for transport in accordance with 49 CFR 178.609(b), must pass a 4.5 m (15 foot) drop test when subjected to free-fall drops onto a rigid, nonresilient, flat, horizontal surface from a height of 4.5 m (15 feet) as specified in 49 CFR 178.609(d),

and in accordance with 178.609(c), 178.609(e), 178.609(f) and 178.609(g), as applicable. Loss of the capability of any inner packaging to retain liquids constitutes failure of the test.

c. OPERATIONAL CONTROLS

(1) NABI must follow their NABI SOP (Standard Operating Procedure) for Plasmapheresis (SOP #N-270G, undated; submitted in the application), for shipments of plasma.

(2) Packages must be transported by contract carrier in a freezer trailer maintained at a temperature of not greater than -20°C. The trailer must be precooled to not greater than -20°C prior to loading. Temperature inside trailer must be monitored and recorded in order to document compliance with the requirements of this exemption.

(3) Package contents must be frozen at all times during transportation.

(4) Packages containing frozen human blood plasma that are subject to this exemption must be segregated from other materials.

(5) Each driver transporting materials under this exemption must be trained on emergency procedure to follow in case of malfunction of the vehicles refrigeration system.

8. SPECIAL PROVISIONS: A current copy of this exemption must be maintained at each NABI donor center participating in the plasma collection program and at the NABI central processing facility.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS: A copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. Section 5101 *et seq.*:

- All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- o Registration required by 49 CFR 107.601 et seq., when applicable.

No person may use or apply this exemption, including display of its number, when the exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (49 CFR 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued at Washington, D.C.:

MAY 30 1997

Alan I. Roberts
Associate Administrator
for Hazardous Materials Safety

(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590-0001. Attention: DHM-31.

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

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