U.S. Department
of Transportation

**Research and
Special Programs
Administration**

AUG 24 1999

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

DOT-E 12285

EXPIRATION DATE: **September 30, 1999**

1. GRANTEE: BBI - Biotech Research Laboratories
Rockville, Maryland

2. PURPOSE AND LIMITATION: This exemption authorizes the transportation in commerce of certain infectious substances in special packagings, transported by a contract carrier. 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 in that an alternative packaging is authorized.

5. BASIS: This exemption is based on the application of Biotech Research Laboratories (BTRL), dated May 28, 1999 and August 20, 1999, submitted in accordance with 49 CFR 107.109.

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, *(Risk Group 1, 2, and 3 materials as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Tenth revised edition)*	6.2	UN2814	(n/a)

7. PACKAGING AND SAFETY CONTROL MEASURES:

a. PACKAGING -

(1) Infectious substances in paragraph 6 that are stored in minus (-)70 °C mechanical and liquid nitrogen freezers must be packed as the follows: (1) watertight cryovials as the primary receptacles; (2) a water-resistant freezer of adequate strength for its capacity, mass and intended use as the outer packaging; and (3) sufficient absorbent material to absorb the entire contents of all primary receptacles.

(2) Primary receptacles must be tightly secured and packed with multi-layered polypropylene sheets within the freezer to prevent the contents from shifting.

(3) Nitrogen freezers must be filled with approximately 4"-6" of liquid nitrogen prior to movement. Mechanical freezers must be filled with sufficient dry ice prior to movement to keep the primary receptacles frozen at all times.

(4) All freezer doors must be securely closed with straps. All freezers must be secured against movement in the transport vehicles.

(5) BTRL will move a total of seventy two (72) (-)70 °C mechanical freezers and thirty one (31) liquid nitrogen freezers under this exemption.

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages containing infectious substances from BTRL's old facilities in Rockville, Maryland to their new facility in Gaithersburg, Maryland. Packages must be prepared by BTRL employees, transported by contract carrier under BTRL supervision, and unpacked by BTRL employees, as outlined in the application for exemption. Materials must be frozen and remain frozen at all times during transportation. Emergency refrigeration procedures must be in place and operational in the event of loss of refrigeration.

(2) The materials in all freezers must be delivered to

the Gaithersburg location within two (2) hours of departure from the Rockville location.

(3) An itemized list of contents must be securely attached to the outside of each freezer.

(4) Emergency responders and back-up equipment necessary to mitigate a spill must accompany each transport vehicle.

8. SPECIAL PROVISIONS:

a. Emergency responders and escorts must carry a copy of packing lists for each freezer.

b. The shipping paper requirements of 49 CFR Part 172 Subpart C and the marking requirements of §§ 172.301(a), (b) and (c) are waived.

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. 5101 et seq:

- All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- Registration required by § 107.601 et seq., when applicable.

Each "hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

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. (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 in Washington, D.C.:

AUG 24 1999

(DATE)

Alan I. Roberts
Associate Administrator
for Hazardous Materials Safety

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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