U.S. Department
of Transportation

**Research and
Special Programs
Administration**

JAN 11 2000

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

DOT-E 12376
(FIRST REVISION)

EXPIRATION DATE: **December 31, 2001**

1. GRANTEE: BBI - Biotech Research Laboratories, Inc.
   Gaithersburg, 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; 49 CFR Part 172, Subpart C in that the shipping paper requirements are waived; and § 172.301(a),(b) and (c) in that the marking requirements are waived.

5. BASIS: This exemption is based on the application of BBI - Biotech Research Laboratories, Inc., dated November 18, 1999, submitted in accordance with § 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, *(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	UN 2814	(n/a)

* No Risk Group 4 materials are authorized for transportation under this exemption.

7. PACKAGING AND SAFETY CONTROL MEASURES:

a. PACKAGING -

Infectious substances in paragraph 6 that are stored in freezers must comply with the following provisions:

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

(ii) Freezers must be filled with sufficient liquid nitrogen and/or dry ice prior to movement to keep the primary receptacles frozen at all times, and sufficient absorbent material to absorb the entire contents of all primary receptacles and any liquid nitrogen in case of an incident.

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

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages containing infectious substances from Biomedical Research Institute, Inc., Rockville, Maryland to the BBI - Biotech Research Laboratories, Inc., Frederick, Maryland. The transportation including transport, loading and unloading must be under the supervision of

BBI - Biotech Research Laboratories, Inc., and performed as specified 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 Frederick location within two (2) hours of departure from Rockville, Maryland.

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

(4) Emergency biological spill equipment and back-up equipment and vehicles necessary to mitigate a spill must accompany the transport vehicles.

8. SPECIAL PROVISIONS: A copy of packing lists for each freezer must accompany the transport vehicles.

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. (Sections 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.:

JAN 11 2000
(DATE)

for Robert A. McGuire
Acting 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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