U.S. Department
of Transportation
**Research and
Special Programs
Administration**

NOV 1 4 2003

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

DOT-E 13257

EXPIRATION DATE: November 30, 2003

1. GRANTEE: Pharmacia Corporation
Kalamazoo, MI

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the one-time, one-way transportation in commerce of certain infectious substances in special packagings, transported by a contract carrier. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.

b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce.

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

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR Subpart C of Part 172 in that the shipping paper requirements are waived; § 172.301 (a), (b) and (c) in that the marking requirements are waived; and § 173.196 in that an alternative package is not authorized, except as specified herein.

5. BASIS: This exemption is based on the application of Pharmacia Corporation dated June 3, 2003 submitted in accordance with § 107.105 and the public proceeding thereon and additional information dated July 15, 2003.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Proper Shipping Name/ Hazardous Materials Description	Hazard Class/ Division	Identi-fication Number	Packing Group
Infectious substances, affecting humans, *(Risk Group 2 materials as defined in § 173.134, as revised, effective February 14, 2003.*	6.2	UN2814	N/A

* No Risk Group 3 and 4 materials are authorized for transportation under this exemption.

7. SAFETY CONTROL MEASURES:

a. PACKAGING- Packaging consists of not more than six (6) large freezers using liquid nitrogen to keep the contents frozen at all times, as described in Pharmacia Corporation's application for exemption on file in the Office of Hazardous Materials Exemptions and Approvals (OHMEA).

b. OPERATIONAL CONTROLS -

(1) This exemption only authorizes the transport of packages containing infectious substances from the Pharmacia Corporation's Research facility in Kalamazoo, MI to the Pharmacia Corporation's, Building 89, Kalamazoo, MI, a distance of approximately ten (10) miles.

(2) Packages must be prepared by Pharmacia Corporation employees, transported by a contract carrier under Pharmacia Corporation supervision in an exclusive-use refrigerated trailer, and unpacked by Pharmacia Corporation employees, as outlined in the application for exemption on file with the OHMEA. The freezers must be loaded on the transport vehicle with oversight from personnel trained in the details of infectious substances in this inventory.

(3) Each freezer must be locked into place within the trailer using metal straps as well as conventional load locking devices to prevent any movement while the shipment is in transit.

(4) The total transit time, including the loading and unloading, should be approximately two (2) hours.

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

(6) Arrangement must be made to have the transport vehicle followed by a trained Emergency Response Team knowledgeable in the lading of the vehicle as well as the contents of each freezer. The Emergency Response Team must have all resources with them to properly respond to any incident that may occur during the transportation phase.

8. SPECIAL PROVISIONS:

a. Emergency responders must carry a copy of the itemized list of contents for each freezer.

b. A current copy of this exemption must be maintained at each facility where the package is offered for transportation.

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

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS: A current 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.:

for Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

NOV 14 2003
(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.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/exemptions Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: AM/GC