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

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

FEB 25 2003

DOT-E 13204

EXPIRATION DATE: July 31, 2003

1. GRANTEE: Esoterix, Inc.
Austin, TX

(See Appendix A to this document for a list of additional grantees.)

2. PURPOSE AND LIMITATION:

a. This emergency exemption authorizes the transportation in commerce of regulated medical waste in film bags that are not marked and certified by the bag manufacturer. 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. The safety analyses did not consider the hazards and risks associated with consumer use or other uses not associated with transportation in commerce.

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

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 172.302(c) in that the packages need not be marked with the exemption number, and 173.197(e)(1)(i) in that the inner packagings must be marked and certified by the manufacturer, except as provided herein.

5. BASIS: This emergency exemption is based on the application of Esoterix, Inc., dated February 14, 2003, submitted in accordance with § 107.117 and a determination that it is necessary to prevent significant economic loss.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper shipping name	**Hazard Class/ Division**	**Identi- fication Number**	**Packing Group**
Regulated medical waste	6.2	UN3291	II

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging must be as authorized in the HMR except that inner film bags are not required to be marked and certified by the bag manufacturer.

b. TESTING - The film bags must be capable of meeting the tests prescribed for tear resistance in ASTM D 1709-01 *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method*, however they need not be marked and certified as such.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modifications or changes are made to the package and it is reoffered for transportation in conformance with this exemption and the HMR.

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

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.

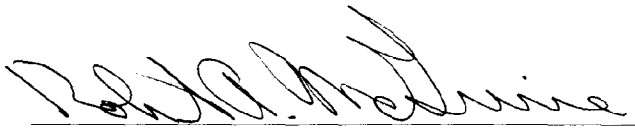
- Registration required by § 107.601 et seq., when applicable.

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 this 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.:



FEB 25 2003

Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, D.C. 20590.
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: DL

MAR 3 1 2003

The following are hereby granted party status to this exemption based on their application(s) submitted in accordance with § 107.107 or § 107.109, as appropriate:

Company Name City/State	Application Date	Issue Date	Expiration Date
Esoterix HQ Austin, TX	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Center for Clinical Trials East Windsor, NJ	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Oncology Centers, Brentwood, TN	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Infectious Disease Centers, San Antonio, TX	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Endocrinology Calabasas Hills, CA	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Coagulation Aurora, CO	Feb 14, 2003	2/25/2003	July 31, 2003
Esoterix Allergy and Asthma Austin, TX	Feb 14, 2003	2/25/2003	July 31, 2003
Lane Memorial Hospital Zachary, LA	Mar 24, 2003	MAR 3 1 2003	July 31, 2003
Long Beach Genetics Rancho Dominguez, CA	Feb 14, 2003	2/25/2003	July 31, 2003

for Ann Mazzullo

Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety