

Hazardous Waste Compliance Data Entry Form - Side A

12/10  
mcc

EPA ID Number: NC D0000010371

Facility Name: TRIMERIS, INC. City: DURHAM

EVALUATION DATA New:  Change:  Delete:

Mo. Day Yr. Type:  
Date: 10 23 02 CEI  
Date:   /  /     

Inspector ID #: 018 Reason: 01

Evaluation Comments: NO VIOLATIONS.

SNC DETERMINATION: If this evaluation resulted in a SNC determination, fill in this block. (NOTE: SNC determinations are SNY/SNN evaluations. The SNY/SNN evaluation can also be submitted later on a separate form.)

Facility is (Check one)  
- a SNC (SNY evaluation) \_\_\_\_\_ Docket # \_\_\_\_\_  
or  
- no longer a SNC (SNN eval.) \_\_\_\_\_

YES / NO CSE ONLY

Waste Involved	Volume	Exposure Media (a, gw, sw, s)	Distance to Residences	Number of People involved	Distance to On-site wells	Distance to Off-site wells

# \_\_\_\_\_ Type: \_\_\_\_\_ Date Determined \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ Class: \_\_\_\_\_  
 Priority: \_\_\_\_\_ Branch: \_\_\_\_\_ Person: \_\_\_\_\_  
 Return to Compliance \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 Reg. Type: \_\_\_\_\_ Reg. Description: \_\_\_\_\_  
 Comment: \_\_\_\_\_

JAN 2003  
ENTERED

# \_\_\_\_\_ Type: \_\_\_\_\_ Date Determined: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ Class: \_\_\_\_\_  
 Priority: \_\_\_\_\_ Branch: \_\_\_\_\_ Person: \_\_\_\_\_  
 Return to Compliance: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 Reg. Type: \_\_\_\_\_ Reg. Description: \_\_\_\_\_  
 Comment: \_\_\_\_\_

STATE OF NORTH CAROLINA  
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES  
DIVISION OF WASTE MANAGEMENT  
HAZARDOUS WASTE SECTION

COMPREHENSIVE EVALUATION INSPECTION (CEI) REPORT

1. FACILITY INFORMATION:

Name: TRIMERIS INC.  
EPA ID Number: NCD 000 010 371  
Type of Facility: LARGE QUANTITY GENERATOR (LQG)  
Facility Location: 4727 UNIVERSITY DR., BLDG. 500  
DURHAM, NC 27707  
Telephone Number: (919) 419-6050  
  
OWNERSHIP: TRIMERIS INC

2. FACILITY CONTACT: CHRIS MCKEEMAN

3. SURVEY PARTICIPANTS: CHRIS MCKEEMAN, MICHAEL HARRIS  
Phillip G. Orozco - NCDENR

4. DATE OF INSPECTION: OCTOBER 23, 2002

5. PURPOSE OF INSPECTION: Unannounced audit to determine compliance with regulations described at 40 CFR 261, 262, 265, 268 and 279.

6. FACILITY DESCRIPTION:

RESEARCH & DEVELOPMENT FOR POTENTIAL HIV <sup>MEDICATIONS</sup> ~~ENR~~  
~~OR REFER TO <sup>HW</sup> MGMT. PLAN INTRODUCTION, ON FILE (ATTACHED.)~~  
BEGAN OPERATIONS IN 1993. ORIG. OPERATED AS A SQG.  
STATUS CHANGED TO LQG IN APRIL 2000. OPERATED AS A LQG  
THROUGH 2001. CHANGED STATUS BACK TO A SQG IN THE  
SPRING OF 2002.

7. HAZARDOUS WASTE STREAMS INCLUDE:

D001 D002 WASTE CHROMIC ACID / CYANURIC CHLORIDE  
F002 F003 LAB SOLVENT WASTE D009  
U003 LAB PACKS U080 METH CHLOR  
P098 POTASSIUM ENCYANIDE  
D003 ACOSOL CAN  
P105 SODIUM AZIDE

8. AREAS OF REVIEW AND INSPECTION :

- ▶ Emergency Preparedness ✓
- ▶ Inspection Records (storage) ✓
- ▶ Training Records April 2001 May 2002
- ▶ Transporters:  
TELISTATE Marine Transport Co. MOO 095 038 998  
ONYX ENV. SVCS NJO 080 631 369
- ▶ TSD's:  
FUSCO INC ARO 049 748 192  
ONYX ENV. SVCS NCD 986 166 338
- ▶ Accumulation Areas:  
LATS 3, 6 AND 9
- ▶ Storage Areas:  
Room 139
- ▶ External Condition of Facility: NO ADVERSE CONDITIONS OBSERVED

✓ Contingency Plan  
Manifests / LDR 2001 & 2002  
Biennial Report SIGNED 3-21-02

9. WASTE MINIMIZATION: GOOD OPERATING PRACTICES

10. SITE DEFICIENCIES:

NO DEFICIENCIES OBSERVED  
NO VIOLATIONS CITED.  
THE FACILITY APPEARS TO BE IN FULL COMPLIANCE WITH  
THE APPLICABLE RCRA RULES.

11. RECOMMENDATIONS:

NONE

Philip G. Orozco DATE: 10-25-02  
PHILIP G. OROZCO  
Waste Management Specialist, NCDENR

COPY OF RPT. MAILED TO FACILITY  
DATE: ON 12-11-02.  
Facility Representative  
PAO

## 1.0 INTRODUCTION

Founded in 1993, Trimeris, Inc. is engaged in the discovery and development of fusion inhibitors, a new class of antiviral drug treatments. Fusion inhibitors impair viral fusion, a complex process by which viruses attach to and penetrate host cells. If a virus cannot enter a host cell, the virus cannot replicate. By inhibiting the fusion process of particular types of viruses, the Company's drug candidates under development offer a novel mechanism of action with the potential to treat a variety of medically important viral diseases. Trimeris is a development stage company. The Company has invested a significant portion of its time and financial resources in the development of T-20, its lead drug candidate. If Trimeris is unable to commercialize T-20, its business will be significantly harmed.

To date, Trimeris has two anti-HIV drug candidates in clinical development. FUZEON™, currently in Phase III clinical trials, is the most advanced compound in development. A New Drug Application (NDA) and Marketing Authorization Application (MAA) have been submitted for FUZEON with the US FDA and EU EMEA, respectively. Trimeris' second fusion inhibitor product candidate, T-1249, has received fast track status from the FDA and is in Phase I/II clinical testing. Trimeris is developing FUZEON and T-1249 in collaboration with F. Hoffmann-La Roche, Ltd.

Trimeris has entered into an agreement with F. Hoffmann-La Roche Ltd (Roche) to develop and market T-20 and T-1249 worldwide. The Company's agreement with Roche grants them an exclusive, worldwide license for T-20 and T-1249 and certain other compounds.

## 2.0 SCOPE & AVAILABILITY OF THE PLAN

The Hazardous Materials and Waste Management Plan applies to Trimeris' Environmental Health and Safety Department. It provides directions for containing, labeling, storage, transportation, inspections, training and record keeping for hazardous waste activities.

## 3.0 RESPONSIBILITIES MATRIX

**Trimeris Hazardous Waste Program Responsibilities Matrix**

Program Element	Action Items	Responsibilities	
		EHS Dept.	Vendors
Hazardous Waste Program Development		X	
Program Implementation			