



September 22, 1997

Ms. Madhulla Logan
Alameda County Environmental Health Services
1131 Harbor Bay Parkway, Suite 250
Alameda, CA 94502-8577

RE: DECONTAMINATION ACTIVITIES
SUPERGEN FACILITY, 6450 HOLLIS STREET, EMERYVILLE, CALIFORNIA

Dear Ms. Logan:

This letter presents additional details regarding facility decontamination activities performed by DECON Environmental Services, Inc., (DECON) at a former laboratory facility operated by Supergen, Inc., (Supergen) at 6450 Hollis Street in Emeryville, California (the Site). The results of the decontamination activities were described in a report by DECON titled *Report of Facility Decontamination Services, Supergen Facility, Emeryville, California*, dated August 29, 1997. The materials and methods used to perform the project were based on information provided by Mr. Joe Iovino and Mr. Donald Ebersman of Supergen regarding the history and uses of the Site. As requested by Mr. Iovino, this letter includes the following details regarding the methods used during the facility decontamination activities:

- The laboratory contained a variety of laboratory equipment, chemical products, and hazardous and non-hazardous wastes. According to Mr. Iovino and Mr. Ebersman, none of the chemical products or wastes in the laboratory were biologically active or infectious (with the exception of a small quantity of bioinfectious waste that was stored in a labeled "BIOHAZARD" container, and which Supergen arranged to have disposed of by a company other than DECON).
- The laboratory contained more than 40 chemical products. Of these, one product (Mitomycin C, or MMC) comprised the majority of the chemical products in the facility. In addition, Supergen provided Material Safety Data Sheets (MSDS) for the products considered by Supergen to be of most concern regarding level of toxicity. Of these, Mr. Ebersman stated that MMC was the most toxic.
- According to Mr. Ebersman and the information on the MSDS provided by Supergen, all the chemical products in the laboratory were organic compounds.
- Following removal of all chemical products from the facility, all remaining objects and surfaces in the room were decontaminated by wet wiping with a solution of sodium hypochlorite (chlorine bleach) in water. Sodium hypochlorite solution is a strong oxidizer and has been shown to effectively break down and dissolve organic compounds.
- The confirmation sampling locations were selected to include the areas that were considered to be most likely to have been exposed to the highest levels of possible contamination. The sample collection and preservation methods were performed in accordance with guidelines provided by the analyzing laboratory, Custom Testing and Development Laboratory (CTD) of Stanton, Delaware. The results of laboratory analysis by CTD indicated that MMC was not detected at or above laboratory detection limits in any of the samples submitted.

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In summary, DECON believes the decontamination methods used for this project were appropriate and effective. If you have any questions regarding this report, please call me at (510) 732-8444.

Sincerely,

William E. Bassett, Jr.
Project Manager

23480 Connecticut Street, Hayward, CA 94545-1607 (510) 732-6444 Fax (510) 782-8584 CL#545726



September 16, 1997

Ms. Madhulla Logan
Hazardous Material Specialist
Alameda County
Environmental Health Services
Environmental Protection (LOP)
1131 Harbor Bay Parkway, Suite 250
Alameda, CA 945-02-6577

Ref: 6450 Hollis Street, Emeryville, CA 94608

Dear Ms. Logan:

Mr. J. Iovino of our organization has asked me to provide the information you requested in your letter of September 11, 1997.

The room at our former quarters, we are concerned with, was primarily a storage area. Drug products prepared at other facilities, or purchased, were stored there for varying lengths of time. The vast majority of products stored, both liquids or solids, were contained in glass vials with rubber stoppers and aluminum seals.

Some limited compounding of investigational products occurred. This activity was carried out in a laminar flow, biohazard, containment chamber. The majority of the activity was carried out using mitomycin. On occasion other materials were repackaged or manipulated, in the containment chamber.

It is important to point out that SuperGen performed no chemical synthesis, manufacturing or analysis at the Hollis St. location.

A table containing information you requested is attached.

The rationale for the testing for mitomycin was based on the high ratio of mitomycin use as compared to other materials. The procedure used in the cleaning process would be effective for the removal of other hazardous materials, thus the mitomycin serves the function of an indicator for the effectiveness of the cleaning procedure.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald S. Ebersman".

Donald S. Ebersman, Ph.D.
Director, Pharmaceutical Development

**EMERYVILLE LABORATORY
INVENTORY**

# UNITS	DRUG	STRENGTH	LOT #	FORM
170 Vials	Mitomycin C	5 mg	1032987	Solid in Vial
170 Vials	Mitomycin C	5 mg	1032985	Solid in Vial
1020 Vials	Mitomycin C	5 mg	1032988	Solid in Vial
170 Vials	Mitomycin C	5 mg	1143220	Solid in Vial
170 Vials	Mitomycin C	5 mg	0343055	Solid in Vial
170 Vials	Mitomycin C	5 mg	0532914	Solid in Vial
170 Vials	Mitomycin C	20 mg	0343059	Solid in Vial
2040 Vials	Mitomycin C	20 mg	1133016	Solid in Vial
15 gr.	Mitomycin		Various batches	Solid
50 gr.	Mitomycin Powder + diluent			Solid
153 Vials	MitoExtra™ Injection	5 mg	0853377	Solid in Vial
122 Vials	MitoExtra™ for Injection	20 mg	0853376	Solid in Vial
1500 gr	Cholesterol			Solid
1900 gr	Cholesterol Acetate			Solid
1000 gr	Glyceryl mono laurate			Solid
500 gr	Tripalymitin			Solid
50 Vials	Doxorubicin	10 mg		Liquid in Vial
30 Vials	Docorubicin	50 mg		Liquid in Vial
2 gr	Podophyllotoxin			Solid
200 mg	Cyclosporine			Powder
500 mL Liquid	Quinomycin Solution			Liquid
20 mL Liquid	Cyclosporin Solution 50 mg/mL			Liquid

EMERYVILLE LABORATORY INVENTORY (COMMERCIAL PACKAGES)

# VIALS	DRUG	STRENGTH	LOT #	FORM
1 each	Urocon Fixative 40 cc Liquid			Liquid
6 Vials	Vinblastine	10 mg	Cetus	Powder in Vial
3 Vials	Methotrexate	10 mg	Iowa	Powder in Vial
500 mg Vials	Cisplatin		India	Powder in Vial
30 Vials	Doxorubicin	10 mg	Commercial	Liquid in Vial
8 Vials	Doxorubicin	50 mg	Commercial	Liquid in Vial
4 Vials	Vincristine	10 mg	Commercial	Powder in Vial
10 Vials	Heparin		Commercial	Liquid in Vial
10 Vials	Compazine		Commercial	Liquid in Vial
12 Vials	Tigan		Commercial	Liquid in Vial
12 Vials	Metoclopramide		Commercial	Liquid in Vial
1 Vial	Albumin, normal serum		Commercial	Liquid in Vial
12 Vials	Lidocaine		Commercial	Liquid in Vial
6 Vials	Keflin		Commercial	Solid in Vial
3 Vials	Cytarabine		Commercial	Solid in Vial
6 vials	Cyclophosphamide		Commercial	Solid in Vial
12 Vials	Doxorubicin		Commercial	Solid in Vial
6 Vials	Fluorouracil		Commercial	Liquid in Vial
3 Vials	Leucovorin		Commercial	Solid in Vial
3 Vials	Amphotericin B		Commercial	Solid in Vial