DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
6000 Metro Drive
Baltimore, MD 21215
410-779-5459

TO

2. NAME AND TITLE OF INDIVIDUAL
K. Paul Thadikonda, Ph.D., President and CEO

3. DATE
09-26-2002

4. FIRM NAME
Eminent Services Corporation

5. HOUR
a.m.
2:30 p.m.

6. NUMBER AND STREET
7495 New Technology Way

7. CITY AND STATE & ZIP CODE
Frederick, MD 21703-9401

8. PHONE # & AREA CODE
240-629-1972

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Candice J. Cortes
George Pyramides

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Candice J. Cortes, Investigator
George Pyramides, Chemist PHI-Lab

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and ******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3001701623

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Dr., Ste 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5705

October 10, 2002

Mr. K. Paul Thadikonda Ph.D., President/CEO
Eminent Services Corporation
7495 New Technology Way
Frederick, Maryland 21703

Dear Mr. Thadikonda:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at Eminent Services Corporation, 7495 New Technology Way, Frederick, Maryland 21703 on August 26 – 29, 2002 by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to April 1, 1997, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and Title 21, Code of Federal Regulations, Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact Karen S. Anthony at (804) 379-1627 Ext. 11 or write to:

Food and Drug Administration
Attention: Karen S. Anthony
10710 Midlothian Turnpike, Ste. 424
Richmond, VA 23235

Sincerely,

Karen S. Anthony
Supervisory CSO
Richmond Resident Post

Enclosure: Establishment Inspection Report

SUMMARY OF FINDINGS

Initial limited inspection of this control-testing laboratory for pharmaceuticals was conducted per FACTS Assignment No.: 245638 and Operational ID: 715370, as a GMP Inspection. This inspection was conducted in accordance with CP 7356.002, Drug Process Inspections, and BLT-DO FY'02 workplans.

GMP coverage of the laboratory during this inspection involved a review of the analytical data for several IND/clinical supplies (API and finished dosage form). Additionally, all SOP's, instrument qualifications/procedures and laboratory functions/operations and stability chamber operations were reviewed.

There were no objectionable observations and a FDA 483 was not issued at the close of the inspection. This inspection was classified NAI.

HISTORY OF BUSINESS

Eminent Services Corporation was begun as a company with incorporation in Maryland December 1997. The firm, which began operations in January 1998, was originally located at 7960 Cessna Avenue, Gaithersburg, MD 20879. They moved to the current site at 7495 New Technology Way, Frederick, MD 21703 during June-August 2002. This was the initial inspection of the firm.

BUSINESS OPERATIONS

The hours of operations are 8:00 a.m. to 5:00 p.m., Monday through Friday. However, staff is present at other hours and days as needed.

The firm is registered with FDA for the current year in accordance with Section 510 of the FD&C Act under Registration Number 3001701623. Attached is a copy of the Registration of Drug Establishment/Labeler Code Assignment (form FDA 2656) issued to the firm, Exhibit GP#1.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

Section written by G. Pyramides/PHI-Lab

On 8/26/2002, we showed our credentials, explained the purpose of the visit and issued an FDA-482, Notice of Inspection, and "Resources for FDA Regulated Businesses" to Krupakar P. Thadikonda, President, and the most responsible firm individual.

I spoke to Krupakar P. Thadikonda, President of Eminent Services Corp., who is responsible for the all operations for the firm. He was available throughout the inspection and was involved in all discussions regarding the firm. During the inspection I also spoke to Kishore B. Gogineni who was the Manager QA/QC. He discussed the Quality Systems operations and reported to Dr. Thadikonda. All laboratory discussions

involved Suneeta Adusumilli, the Technical Director. She was the chief scientist who supervised and reviewed all of the chemical analysis.

All Persons I Spoke To

Krupakar P. Thadikonda "Paul", President and CEO of Eminent Services Corporation. He is the most responsible person on site. He was present during the whole inspection and was knowledgeable about all aspects of the operation of the firm.

Vijaya L. Thadikonda, – Vice President, Mrs. Thadikonda (wife of Krupakar Thadikonda) is responsible for all administrative functions for the firm. There were limited discussions with her.

Kishore B. Gogineni – Manager QA/QC, - Mr. Gogineni was present throughout the inspection. He was the responsible for the Quality Functions of the company. Discussions of any QA/QC operations included him.

Suneeta Adusumilli – Technical Director, Chief Scientist for the laboratory group. She conducted much of the analytical data reviewed and was responsible for all laboratory operations. She responded to most of the chemistry questions.

Marc Edwards – Operation Manager. Mr. Edwards was responsible for all operations involving the warehouse and clinical supplies. He was involved in discussions concerning the warehouse and the support staff for the clinical supplies.

A copy of the firm's organization chart is shown in Exhibit GP#3.

All post-inspectional correspondence should be forwarded to Krupakar P. Thadikonda, President and CEO of Eminent Services Corporation, 7495 New Technology Way, Frederick, MD 21703.

OPERATIONS

The firm is located in a two story building in an industrial park. The firm occupies a space of approximately 60,000 square feet. The firm's building had a large warehouse area (31,000 ft^2) that took up a majority of the facility and a smaller laboratory area (2,500 ft^2). Administrative areas accounted for approximately 23,500 ft^2. The second story of the building was not being used at the time of this inspection. According to the firm, the second level was the expansion area for a new spin off company called Eminent Biopharmaceutical Services. The firm stated that this business operation will assist companies launch new drug products into the market and obtain insurance reimbursement. A floor plan of the facility is shown in Exhibit GP#2.

The firm's operations at the time of inspection included IND/clinical supply of drugs, formulation of dosage forms and analytical services (method development, release testing and stability testing). No manufacturing operations were being conducted at the time of

the inspection. The firm had manufacturing capabilities at the previous site and were currently preparing for manufacturing operations. At the time the inspection, some manufacturing equipment was present but not yet qualified. During the walk-through tour of the site, several of the areas in the warehouse were pointed out as expected locations for manufacturing processes. The warehouse area, including where the pharmaceutical materials were stored, was climate controlled with air conditioning and heating. Two rooms constructed in the warehouse were designated as API and bulk materials weighing rooms but were not yet qualified.

Laboratory Overview
Section written by G. Pyramides/PHI-Lab

The laboratory was located in one large room with associated smaller auxiliary rooms used for weighting and sample preparations. All the analytical testing took place in this room on the first floor of the facility. The room was open in the center with benches along the walls where the instrumentation was located.

The lead scientist for the laboratory was Suneeta Adusumilli who was assisted by several analytical staff. The laboratory group was compact with responsibility for many of the functions shared by members of the firm.

The laboratory was equipped with the following instrumentation: two Waters HPLC (one with Diode Array UV/Vis Detector, the other with single channel UV/Vis detector), Perkin Elmer FT-IR (infrared spectrometer), DigiPol Polarimeter, Perkin Elmer Lambda2 UV/Vis spectrophotometer, Brinkman Automatic Titrator, Dissolution Apparatus, Varian Gas Chromatograph, Melting Point Apparatus and assorted balances, ovens and small laboratory apparatus.

I reviewed the calibration and maintenance records for the HPLC's, Infrared Spectrometer, UV/Vis Spectrophotometer, Dissolution Apparatus and Gas Chromatograph. The firm conducted appropriate calibrations at suitable intervals. The laboratory was orderly and organized and the instruments appeared to be in good operational condition and well maintained.

I reviewed a list of all Standard Operating Procedures (SOPs) and selected the relevant laboratory procedures for review. The SOP's covered all the topics typically found in pharmaceutical analytical laboratories. Included training, sample/standard handling, instrument operation and calibration, OOS handling, specific analytical SOP's associated with product analysis, validation of methods, and document change control. I reviewed all the analytical SOP's.

Drug Stability Chambers Review
Section written by G. Pyramides/PHI-Lab

The firm had stability operations ongoing at the time of the inspection. A large portion of the firm's laboratory operations included stability analysis. The firm had several stand-alone stability chambers and a large refrigerated walk in chamber.

The stability chambers included: ICH guideline - 25C/60%RH, Walk-In 3 degrees C Refrigerator, -85 C Freezer chest, 2 Accelerated Conditions Chambers - 40C/75%RH and several chambers that were not in use and not powered during the inspection.

I reviewed the temperature and relative humidity mapping study and results from the validation for the large walk-in refrigerator and the ultra low temperature chamber (-85 C). The firm used a large number of test locations and conducted extensive mapping of the conditions in the chambers. The mapping study demonstrated the uniform temperature control of the chambers.

IND Clinical Supply/Warehouse Overview
Section written by G. Pyramides/PHI-Lab

The warehouse areas were active with clinical supply activities. Clinical drug supplies were stored and shipped during the inspection. The firm's staff received drug study requests via FAX and would organize the materials, pack the items and ship to the appropriate individuals or study locations.

I reviewed the receipt, identification and logging in, storage location determination and tracking, selection and distribution procedures for the clinical supply operations. I reviewed the computerized database system which resided on the firms in-house Local Area Network (LAN). I conducted a review of the responsibilities and control functions of the computerized database system by selecting a sample from the warehouse storage area and tracking it from receipt to shipment. The firm's database operations were suitable for intended use. A limited review of the computer validations of the LAN based database system was performed.

Analytical Data Reviewed
Section written by G. Pyramides/PHI-Lab

I selected several API's and profile classes of drugs for review of the raw data. The data consisted of Assay, Impurity and qualitative tests, sample/standard preparations and results. The drugs I reviewed were all IND/clinical supplies. They are listed below:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

DISCUSSION ITEMS

No items were discussed with management.

ATTACHMENTS

1. FDA 482, Notice of Inspection, dated 8/26/02, 1 page.

EXHIBITS

GP#1 – Copy of FDA Registration of Drug Establishment/Labeler Code Assignment (Form FDA 2656), dated 07/29/ 2002. This form was the response to the address change.

GP#2 – Copy of the floor plan of the facility inspected. Each area of the operation is identified.

GP#3 – Eminent Services Corporation Organizational Structure Chart. This represents the structure and organization of the firm at the time of the inspection.

George Pyramides
Chemist
PHI-LAB

Candice J. Cortes
Investigator
Baltimore District Office