DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
6000 Metro Drive, Suite 101
Baltimore, MD 21215
410-779-5454

TO

2. NAME AND TITLE OF INDIVIDUAL
K. Paul Thadikonda, Ph.d., President & CEO.

3. DATE
3/7/06

4. FIRM NAME
Eminent Services Corporation

5. HOUR
10:30 a.m.
p.m.

6. NUMBER AND STREET
7495 New Technology Way

7. CITY AND STATE & ZIP CODE
Frederick MD 21703

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))*

Douglas A. Campbell

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*

DOUGLAS A. CAMPBELL, CSO.

[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 pre- scribed 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

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

FEI: 3001701623

April 28, 2006

Eminent Services Corporation
Attn: Dr. K. Paul Thadikonda, Ph.D,
President & CEO
7495 New Technology Way
Frederick, MD 21703

Dear Dr. Thadikonda:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises Eminent Services Corporation, 7495 New Technology Way, Frederick, MD 21703-9401, on March 7 & 9, 2006, by 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 the 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 Federal Regulations, Part 20. This, however, does not preclude you from requesting, and possibly obtaining any additional information under the FOIA.

If there is any question about the released information, feel free to contact Kirk Sooter at (410) 779-5454 or write to: Food and Drug Administration, Attention: Kirk Sooter, 6000 Metro Drive, Ste. 101, Baltimore, MD 21215.

Sincerely,

Evelyn Bonnin
Director, Baltimore District Office

Enclosure

TABLE OF CONTENTS

SUMMARY 1
ADMINISTRATIVE DATA 2
HISTORY 2
INTERSTATE COMMERCE 3
JURISDICTION 3
INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED 3
FIRM'S TRAINING PROGRAM 3
MANUFACTURING/DESIGN OPERATIONS 3
MANUFACTURING CODES 8
COMPLAINTS 8
RECALL PROCEDURES 8
OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE 9
REFUSALS 9
GENERAL DISCUSSION WITH MANAGEMENT 9
ADDITIONAL INFORMATION 9
SAMPLES COLLECTED 9
VOLUNTARY CORRECTIONS 9
EXHIBITS COLLECTED 10
ATTACHMENTS 10

SUMMARY

The limited inspection of this contract drug (clinical products only) research/manufacturing/repackaging/relabeling firm was conducted in accordance with BLT-DO workplans for FY '06, Compliance Program 7356.002 "Drug Manufacturing Inspections", and was designated with FACTS Assignment ID: 670357 and Operation ID: 2555077. The previous inspection was conducted on 4/2/2003 by BLT-DO, per a directed assignment request from CDER, and was classified [redacted].

This firm provides contract services for Investigational Drug Management, including drug product development through the NDA submission process. The primary operations (80%) are packaging and labeling drug products for distribution to sites (domestic and international) for use in clinical studies. Approximately 50% of these distribution operations are under contract with U.S. Government agencies. The scope of this inspection included a review of the computer system, which controls all aspects of the firm's operations, and the packaging and labeling operations. The laboratory system was not covered during this inspection. Records reviewed include: quality

system records (complaints, investigations, etc.), validation/qualification records, and batch production records.

During the inspection, no objectionable conditions or deficiencies were noted, and no FDA 483 was issued. There were no refusals, and no samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Eminent Services Corporation
Location:	7495 New Technology Way Frederick, MD 21703-9401
Phone:	(240) 629-1972
FAX:	
Mailing address:	7495 New Technology Way Frederick, MD 21703-9401
Dates of inspection:	3/7/2006, 3/9/2006
Days in the facility:	2
Participants:	Douglas A. Campbell, Investigator

Upon arrival at the firm, the FDA 482 "Notice of Inspection" was issued to K. Paul Thadikonda, Ph.D., President and CEO.

HISTORY

The history information for this firm remains as previously reported in the EIR from the April 2003 inspection. In general, Eminent Services Corporation is an S-Corp, registered in Maryland and established in 1997. The firm has been operating from the current address since 2002.

FMD Correspondence should be directed to:

Dr. K. Paul Thadikonda, Ph.D, President & CEO
7495 New Technology Way
Frederick, MD 21703

There is no history of regulatory actions regarding this firm. There have been no recalls since the last inspection.

The firm is currently registered as a drug manufacturer.

The firm provides contract services for [redacted] (private) and National Institute of Health (NIH) (government).

INTERSTATE COMMERCE

Drug products are shipped directly to sites (dictated by sponsor) for use in investigational drug clinical studies. Interstate commerce is estimated at 95%. **NOTE:** These products are not for sale.

JURISDICTION

Currently, this firm does not market commercial products. There have been instances where the firm stored and shipped commercial product for distribution in Sweden.

No labeling was collected during this inspection.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The information for this report was primarily provided by Dr. Thadikonda and Arun R. Kantareddy, Vice President. Janakidevi Kora, QA/QC Manager also provided information for this report. Identified as **Exhibit #DAC-1** is the organizational chart for this firm. Dr. Thadikonda is directly involved in the day-to-day operations at the firm. Identified as **Exhibit #DAC-2** are the position descriptions for Vice President (the document states "Director, IT Operations", however, the firm recently changed the title) and Manager, QA/QC.

FIRM'S TRAINING PROGRAM

The firm has 23 employees. The firm's training files are maintained electronically on the firm's Intranet. During the demonstration of the computer systems utilized by the firm, I reviewed the file for A.S., Packaging Operator. There were no deficiencies to report.

MANUFACTURING/DESIGN OPERATIONS

During this inspection, the firm was not actively conducting manufacturing or packaging operations. The Quality System, Materials System, Facilities and Equipment System, Production System, and the Packaging and Labeling System were all covered, indirectly, during the demonstration of the Investigational Drug Management System (IDMS) given by Dr. Thadikonda and Mr. Kantareddy.

Currently, the firm's only manufacturing operations involve the manufacture of placebo products to include in the packaging of the investigational drug products for use in clinical studies. Primarily, the operations involve packaging kits which contain the placebo and investigational new drug products, which are provided by a contract manufacturer. The packaging operations are configured to provide for the randomization scheme (i.e., single blind, double blind) dictated by the contract sponsor (this firm can provide the randomization scheme for the sponsor).

Most of the labeling (98%) is printed at the firm, from a master template that has been approved by the sponsor. The products can be held in temperature-controlled conditions upon receipt and before shipment. Many of the drug products that are distributed by the firm must be shipped in temperature-controlled conditions. The firm has conducted their own transit studies to ensure that the products can maintain the required conditions throughout the distribution process. I did not review these transit studies during this inspection.

The IDMS was developed by Mr. Kantareddy and Dr. Thadikonda. During the inspection, a demonstration provided examples of how the system controls all aspects of the firm's operations. The system was operated in "Demo" mode. Dr. Thadikonda stated that the system would be used in this mode to conduct training. The following modules were reviewed:

Location Registration
- used for inventory of all materials

Unit Registration
- unit of measure for the products

Drug Registration
- all components, materials, etc. associated with the drug product

Drug Allocation
- used for every client, it tracks the bulk from the contract manufacturer through the allocation for the studies (references the randomization scheme)

Protocol Registration

Regulatory Mangement Module
- used to track any Adverse Drug Events (ADE)

Site Registration
- includes sponsor, consignee, and investigators for each study protocol

Vendor Registration
- for all suppliers of drug products, components, packaging, etc.

Investigator Registration

Consignee Registration

Clinical Site Contact and Initiation

- correlation for the protocol, consignee, and investigation
- all must be valid before shipment is released

Receiving Header Registration

- for vendors or clinical sites (returns)

Receiving

- documentation for initial inspection (quarantine status), storage conditions, and location
- samples are collected and identified with a Sample ID# which is different for each item and is used for traceability
- the information is reviewed by a second person, a Receiving Inspection Report is generated for each sample, and upon acceptable results, the material is available in the inventory

Shipping

- An Agent Request Form is generated and information regarding the shipment is collected and entered into the system
- All of the information must be checked and approved before a Packing Slip can be printed.
- The Packing Slip is generated with a bar code. The bar code is used to integrate the IDMS with the shipping carrier's (FedEx, UPS) tracking system. The tracking information is transferred into the IDMS.

Inventory Reconciliation

- zero tolerance; if the count is off by one unit, the client will be notified.

Batch Records

- Manufacturing
- Packaging and Labeling
- Dispensing
- The system maintains a protocol for each product and a master formula for components as a template based on the product
- The system builds the batch record, generates the Batch #, picks the components from the available inventory within the system (First-in-First-Out or First-Expiry-First-Out)
- Instructions are pulled from a database, product-specific master file
- A Shipping Request is generated for the transfer of specific components, dictated by the batch record, from the warehouse to the production area

- A Packing Slip is generated with a Shipping Type = T (for Transfer)
- A Packing Room Cleaning Certificate is generated by the system for pre and post opera documentation
- The finished product is received into the warehouse through the Receiving Module and inventory is updated accordingly
- Release is approved by QA (and in some cases the Sponsor)

Labeling

- a Label Request is generated
- the IDMS contains a master label (approved by the sponsor) and transfers specific information, i.e., protocol#, expiration date, etc. to the label for printing

Supplies

- maintains inventory of administrative supplies

Email Scheduler

- each day, gathers information for any shipments (with tracking numbers) and sends em the consignee
- a monthly report with details of all activities is generated and sent to each client

Calibration

- maintains the status/frequency/results for all equipment
- the system generates the sticker to be affixed on each piece of equipment

Facility Environmental Monitoring

- thermocouples throughout the facility, in temperature-controlled storage, and the stabili chambers
- continuous monitoring with printed results every 30 minutes
- QA review of hardcopy from previous day

Recall

Laboratory Testing

- database of all tests which can be performed
- test methods maintained on intranet, with hardcopy on file
- separated by test procedure or stability protocol
- results are manually entered into the validated MS Excel Spreadsheet; references noteb

- color-coded screens differentiate new, approved, and edited data; any changes are captured and reported on the COA
- limited access for QA/QC activities; QA will cross-reference the notebook and the data entered into the system
- with approval, the system will print the COA for the sample
- Sample Registration generates the transfer tracking

Stability Protocols

- the system sends an e-mail to the Laboratory Director (and others) with a list of all samples which are scheduled to be pulled for that day
- the system tracks all pulls and testing results

Deviation/Incident

- the system generates and maintains the Deviation/Incident Log
- the firm uses this module to track and trend deviations/incidents
- there were 61 reports for 2005

Dr. Thadikonda stated that the system has the capability to support Part 11-Compliant electronic copies of the documentation; however, all documentation would be maintained in hardcopy at the firm. I reviewed the Validation Report for Investigational Drug Management System IDMS 2001, Version 1.0. This validation was conducted in 2001 when the system was upgraded to SEQUL and Visual Basic servers. This report included summary sheets of the executed protocol. There were no deficiencies to report.

At the time of the inspection, the validation for the IDMS Version 2.0 was ongoing and nearly completed, with a scheduled launch in July 2006. An in-house source code review was conducted by Mr. Kantareddy. I reviewed portions of the executed protocol, which included tests for security/access challenges and to ensure that quarantined product was not available for shipment. There were no deficiencies to report.

I reviewed the IDMS Laboratory MS Excel Spreadsheet Validation, dated August 2005. This validation was conducted when the spreadsheets were integrated for use with laboratory calculations. A test was conducted for each type of spreadsheet used (assay, LOD, etc.), and manual calculations were used to verify the spreadsheet calculations. There were no deficiencies to report.

The firm's intranet maintains all SOPs and Test Methods (including obsolete versions), and documents all revisions. In addition, the Employee Training Files are maintained on the intranet.

The firm has a series of manufacturing/packaging suites within the facility. I reviewed the Blister Packing Machine (BP105-MF) Qualification Protocol, dated May 2004. This report provided information regarding the Installation, Operational, and Performance Qualification. The PQ included a verification of the safety interlocks, which control the hoppers (4), and a verification of the Non-fill Detection (NFD) system. The batch record provided instructions for configuration of the hoppers to meet the requirements of the randomization scheme. For verification, samples were collected and submitted to the laboratory for visual inspection and an identity test of the product. All results were within specifications. There were no deficiencies to report.

I reviewed the Packaging & Labeling Batch Record, Batch #05B0064, January 2005. This record included examples of the labeling for the primary and secondary packaging, and documentation of a 100% visual inspection (manual) of the patient-specific drug code on each unit. I reviewed the Packaging & Labeling Record, Batch #05B0063, January 2005. The placebo and active drug product are packaged separately and then combined in the kit based on the randomization scheme for that study. I reviewed the Manufacturing Record, Batch 04B0307, June 2004. This documented that manufacture of capsules and included Deviation/Incident Report #04D0033. There were no deficiencies to report.

MANUFACTURING CODES

Each batch record has a unique number: 05B0064

05 – Year

B – Batch Record

0064 – sequential number

COMPLAINTS

The Complaint Module was included in the demonstration of the IDMS. This included the Customer Complaint Log. Information about the complaint is manually entered into the system, with an audit trail, and the record is given a unique number. All customer complaints are entered into the firm's Corrective Action/Preventive Action (CAPA) system. QA will track and trend the complaints from the log, with reports at the monthly QA meeting. There were 36 complaints for 2005. I reviewed Customer Complaint #05C0036 (electronic), dated 8/22/2005. There were no deficiencies to report.

RECALL PROCEDURES

The Recall Module was included in the demonstration of the IDMS. Dr. Thadikonda stated that based on the expiration date of the products, new products are shipped to replace the expiring product at the sites of the clinical studies. The system will generate correspondence (e-mail) for each site based on the shipment history. If the clinical sites do not respond, Eminent Services Corporation will contact the sponsor for that study.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

During the inspection, no objectionable conditions or deficiencies were observed, and no FDA 483 was issued.

REFUSALS

None

GENERAL DISCUSSION WITH MANAGEMENT

Dr. K. Paul Thadikonda, Ph.D., President & CEO, Arun R. Kantareddy, Vice President, and Janakidevi Kora, Manager QA/QC were in attendance for the firm at the closeout meeting. During this meeting, Dr. Thadkikonda was informed that his compliance status was acceptable, and that given the nature of the current operations, his drug registration would be changed to "voluntary".

ADDITIONAL INFORMATION

During the inspection, I spoke with Monica Caphart, CDER, Office of Compliance. She stated that because this firm is involved exclusively with investigational new drug products, the firm would not be required to register or provide a list of the drugs handled by the firm. In addition, she stated that the firm should not be placed in the biennial-GMP inspection program for the district. After discussion within the BLT-DO Drug Cadre and with BLT-DO Management, the firm will be categorized as a warehouse in FACTS. If the firm's operations change and begin to involve commercially-marketed drug products, an inspection request will be triggered through EES.

This firm also operates as a mail order pharmacy. These operations are conducted under a license by the Maryland Board of Pharmacy and under contract through the National Organization for Rare Diseases (NARD). NARD will qualify the patient, maintain and provide Eminent Services Corporation with the physician prescription/patient information, and coordinate the shipment of the supplies to Eminent Services Corporation. The most recent Maryland Board of Pharmacy inspection was conducted on 5/4/2004.

Michael Duran, SCSO Nashville, TN Resident Post was contacted via email with information regarding a contract manufacturer for the sterile products which are distributed by this firm. Sterile drug products are manufactured, under contract, by the University of Tennessee, College of Pharmacy, Parenteral Medication Laboratory, Memphis, TN. At the time of the inspection, there was no information regarding this firm in FACTS.

SAMPLES COLLECTED

None

VOLUNTARY CORRECTIONS

None

EXHIBITS COLLECTED

DAC-1 Organizational Chart
DAC-2 Position descriptions for Vice President and Manager, QA/QC

ATTACHMENTS

FDA 482 "Notice of Inspection", dated 3/7/2006

Douglas A. Campbell, Investigator
Baltimore District