

Paul Thadikonda
President & CEO
Eminent Service Corporation
7495 New Technology Way
Frederick, MD 21703-9401
USA

Re: Draft inspection report

Dear Mr Thadikonda,
Please find attached our draft report from our inspection of [REDACTED] at your site.

You may correct facts if we have made any mistakes. Please respond with your plan for corrective actions no later than 29 of September 2002. Thanks for your co-operation.

Yours sincerely,


Siv Asplund Peiró
Expert

Copies:
[REDACTED]
[REDACTED]

Attachment: Draft report



2002-09-12

EMEA/H/C/369
24:2002/45523

Drug Inspectorate
L. Hamilton

GMP INSPECTION REPORT

Inspected site:

Eminent Services Corporation
7495 New Technology Way
Frederick, MD 21703-9401
USA
Phone: +1 240 629 1972 Fax: +1 240 629 3298

Activities Carried out by company

- Manufacture of Active Ingredient
- Manufacture of Finished Medicinal Product
- Manufacture of Intermediate or bulk
- Packaging
- Importing
- Laboratory Testing
- Batch Control and Batch Release
- Other: Storage and Distribution

Inspection dates:

2002-08-30

Inspectors:

Ms Lilian Hamilton, principal pharmaceutical inspector, Medical Products Agency (MPA), Sweden
Ms Siv Asplund Peiró, expert, Medical Products Agency (MPA), Sweden

References:

██████████, EMEA application number EMEA/H/C/369

Introduction:

Eminent Services Corporation provides contract services to pharmaceutical industry. Dr K. Paul Thadikonda started the firm in 1998. Eminent Biopharmaceuticals is a joint venture with ██████████ for distribution. The activity proceeds in Frederick since 2002-07-01 and 15 persons are employed. Other services than the actual storage and distribution for ██████████ are assisting companies in clinical studies of drugs.

This was the first inspection carried out by a competent authority of EU.

FDA was informed about the inspection. However they did not take part.



2(5)

Scope of Inspection: Brief report of the inspection activities undertaken:
The inspection was the first EU inspection of the site and covered the storage and distribution of the product [REDACTED] which is classified as an orphan drug.

Inspected areas: The areas inspected were products receiving, storage, shipping and review of documents.

Personnel met during the inspection: A list of personnel met during the inspection is enclosed as annex 1.

Quality Management: Inspectors Team's findings and observations relevant to the inspection:
Eminent has a QA/QC manager responsible for the Quality System including final approval of documents and release of products. The QA/QC is independent of Production and reports to President & CEO. Organisational chart is included in the Site Master File.

Personnel: Personnel are experienced and well trained.

Premises and Equipment: Eminent Services Corporation has recently moved to an existing, free-standing brick building. There is a card system for access in place. However it was not yet operational. The building has a warehouse of 37 000 square feet and a two-floor office of 26 000 square feet. The total facility is equipped with HVAC system. The HVAC system and storage equipment such as the two refrigerators are under a maintenance plan. Eminent is not currently involved in manufacture of commercial pharmaceutical formulations. Eminent has contracted private vendors to maintain the facility and to provide pest control services.

Documentation: The following documents were reviewed:

- SOPs on general maintenance, employee training, product recalls, internal audits, incoming shipment receipt procedure, agent storage/handling, shipping/transfer procedures, shipments-refrigerant brick/gel packs, quarantine and release procedures
- Training files, job descriptions
- Validation of distribution of temperature in refrigerators, the temperature monitoring system and the alarm system.

Production: [REDACTED] in vials are received from [REDACTED] with FedEx packed to maintain +2 to +8 °C in cardboard boxes. At the receiving Eminent checks that no vials are broken. Storage takes place in walk-in refrigerators. Storage temperatures are monitored.

Quality Control: Visual inspection of vials was performed at receiving.

Contract Manufacture and Analysis: Eminent Services Corporation is a contract acceptor. The contract/technical agreement with [REDACTED] was reviewed at [REDACTED]. [REDACTED] There are no subcontracts.

3(5)

Complaints and Product Recall: There have been no recalls of [REDACTED]. [REDACTED] is responsible for handling complaints and product recalls. Eminent will perform investigations if necessary. There have been no such investigations due to complaints so far. Eminent has complaint and product recall procedures. However it was not evident that they also are valid for commercial products.

Self Inspection: There is a programme in place for self inspections.

Distribution and Shipment: Shipment to Sweden is requested by fax from [REDACTED]. Three boxes are packed in one igloo with gel packs. The goods are sent by car to the airport for transport by plane to Stockholm and by car to Inpac, Lund. The transport takes 18 hours and an additional 24 hours at Customs. The igloos are validated to hold the temperature limit for 96 hours. The most current delivery date was 2002-08-19.

Questions raised relating to the assessment of a marketing application: Not applicable

Site Master File: A Site Master File was sent to MPA prior to the inspection. The Site Master File is dated August 2002. The content of the Site Master File was in line with observations made during the inspection by the inspection team.

Samples taken: Miscellaneous:
No samples were taken.

Distribution of Report: Original to EMEA
Copies:
Filed at MPA
Eminent, Frederick, att. Paul Thadikonda
[REDACTED]
[REDACTED]

Annexes attached: Annex 1: List of personnel met during the inspection
To be completed when response is received and reviewed.

List of Deficiencies

Critical deficiencies: No critical deficiencies were observed.

Major deficiencies: No major deficiencies were observed.

Other deficiencies
Premises and Equipment:

1. The access to the computer room was not controlled. (EU-GMP, annex 11 p 8)
2. Area for returned goods was not physically segregated or marked as such. (EU-GMP 3.23)

Documentation:

3. It was not clear if the SOP for recalls was also valid for commercial products. (EU-GMP 8.9)

4(5)

Recommendations:

The inspection team recommends that the Site should be accepted for storage and shipping of [REDACTED]

Summary and conclusions:

To be completed when draft has been reviewed.

Names

Lilian Hamilton

Siv Asplund Peiró

Signatures

Organisation

MPA

MPA

Date

Annex 1.

Personnel met during the inspection

From Eminent Service Corporation

Mr Paul Thadikonda	President & CEO
Mr Kishore Gogineni	Manager QA/QC
Mr Marc Edwards	IDR Manager

[REDACTED]
[REDACTED]
Mr Göran Kvist

[REDACTED]
Qualified Person, Sweden

EMINENT
SERVICES CORPORATION

7495 NEA TECHNOLOGY WAY
FREDERICK, MD 21703-9401
P.240.629.1972
F.240.629.3299

September 28, 2002

Siv Asplund Peiro
Lakemedelsverket
Medical Products Agency
Box 26
S-751 03 Uppsala
SWEDEN

Re: Response to Audit Report dated September 13, 2002

Dear Ms. Peiro:

Thank you for sending the draft Audit Report for the audit performed on August 30, 2002 by Ms. Lilian Hamilton and you. I have reviewed the above referred report and found to be acceptable. All the deficiencies indicated in your report were corrected as of September 19, 2002. The following are formal responses to each of the deficiency listed in the report.

1. *The Access to computer room was not controlled (EU-GMP, annex 11 p 8).*

EMINENT is relatively a small company with only 15 staff members. The overall EMINENT's facility is monitored by electronic security 24-hours-a-day and seven-days-a-week. All staff members are very well trained in the activities that EMINENT performs. Access to general areas within the facility is not restricted to employees.

Access to Computer room is always limited to Systems Administrator and the Management. Access to all client stations as well as servers throughout EMINENT facility is pass-word protected and the security is administered through Microsoft Back-Office Server running on Windows 2000 Server Technology.

EMINENT Computer Server Room is now kept locked 24-hours-a-day with effect from August 30, 2002.

2. *Area for returned goods was not physically segregated or marked as such (EU-GMP 3.23)*

EMINENT has recently relocated to this new facility. Pending for permits from Frederick County Government to do certain alterations in the building, returns are being processed at the far-end of the warehouse in a segregated area. However, the returns area is now marked with a sign "RETURNS/REJECTS" as of September 4, 2002.

The Pre-EMINENT Provider of Pharmaceutical & Info Tech Services



3. *It was not clear if the SOP for recalls was also valid for commercial products (EU-GMP 8.9).*

The *EMINENT SOP# 6013 (Study Product Recall)* was renamed as *Drug Product Recall* and working was revised to include the commercial drugs with effect from September 19, 2002.

If you have any further questions or in need of additional information do not hesitate to call me at (240) 629-1972. Thank You.

Sincerely,



K. Paul Thadikonda, PhD
President & CEO



Paul Thadikonda
President & CEO
Eminent Service Corporation
7495 New Technology Way
Frederick, MD 21703-9401
USA

COPY

Re: Response to draft inspection report

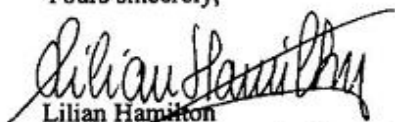
Dear Mr Thadikonda,

Thank you for the response to our draft report from our inspection of [REDACTED] at your site.

We have reviewed your plan for corrective actions and found it to be acceptable. Based on your response and our observations during the inspection we conclude that your company is found to operate in accordance with the EU-GMP. The report will be finalised and sent to EMEA.

Thanks for your co-operation.

Yours sincerely,


Lilian Hamilton
Principal Pharmaceutical Inspector

Copies:
[REDACTED]
[REDACTED]