DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

TO
2. NAME AND TITLE OF INDIVIDUAL
K. Paul THADIKONDA, PHD, President + CEO

3. DATE
April 2, 2003

4. FIRM NAME
EMINENT Services Corporation

5. HOUR
905 (a.m.)
(p.m.)

6. NUMBER AND STREET
7495 New Technology Way

7. CITY AND STATE & ZIP CODE
FREDERICK, MARYLAND 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))*
Lynette P. Salisbury
Sriram Subramaniam

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
LYNETTE P. SALISBURY, INVESTIGATOR
SRIRAM SUBRAMANIAM, Ph.D.
TAMAL K. CHAKRABORTI, Ph.D.

[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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baetimore, Maryland 21215 (410) 779-5454	April 2, 2003 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: K. Paul Thadikonda, Ph.D. President and CEO

FIRM NAME	STREET ADDRESS
EMINENT SERVICES Corporation	7495 New Technology Way
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Frederick, Maryland 21703	Pharmaceutical Facility

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Failure to assure the lot number of the test product ([redacted], 10 mg) received at Eminent for study # CLO-0199 [redacted] shipment records indicate the lot number of the test product as 019011, where as Eminent's receiving and Packaging Slips and Batch record indicate the lot number as 019011A.

LPS 4/2/03

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lynette P. Salisbury	Lynette P. Salisbury, Investigator Sriram Subramaniam, Ph.D. Tamal K. Chaigrabort	4/2/03

FORM FDA 483 (8/00) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 1 PAGES

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EMINENT
SERVICES CORPORATION

7495 NEW TECHNOLOGY WAY
FREDERICK, MD 21703-8401
P 240 629 1972
F 240 629 1298

May 08, 2003

The District Director
Department of Health and Human Services
Food and Drug Administration
6000 Metro Drive Suite 101
Baltimore, Maryland 21215

Ref: FORM FDA 483 Inspectional Observations Page 1 of 1
Dated April 2, 2003

Dear Sir:

EMINENT Services Corporation is (EMINENT) pleased to submit the following response along with pertinent supporting documents to the Inspectional Observation cited on Form FDA 483 during the audit conducted on April 2, 2003

Observation:

1. *Failure to Assure the lot number of the test product ([redacted]) received at Eminent for Study # [redacted]. [redacted] shipment records indicate the lot number of the test product as 019011, where as Eminent's receiving and packaging slips and Batch record indicate the lot number as 019011A.*

Response:

During the receiving inspection EMINENT personnel inspected the receipt of [redacted], 10 mg (manufactured by [redacted]) on March 14, 2001 with Receipt Number 01R0281 and EMINENT Sample # 015-0005 and recorded the Lot Number "019011" as appeared in accompanied documentation. Since the product is intended for double blinded studies, the actual product was not labeled.

Though the documentation accompanied the shipment has the lot number as "019011", on March 22, 2001, while issuing the components for packaging and labeling operations for BR# 01B0081, EMINENT noticed that the lot number was printed as "019011A" on the outer shipper containing the product. EMINENT staff verified the discrepancy with [redacted], QA Representative o[redacted], who is present during the packaging and labeling operations. [redacted] assured that the product lot number is "019011" and the additional letter "A" represents the packaging operation. Upon his assurance the lot number was corrected to "019011A" in the Receiving Slip, Packing Slip, and the Batch Record.

Please find an attached letter dated April 3, 2003, from [redacted], Clinical Research Manager, [redacted] with explanation relating to the procedures followed by [redacted] in issuing the lot numbers as well as providing assurance that the production lot number of the product is "019011" and the packaging lot number is "019011A".

If further information is needed do not hesitate to call me at (240) 629-1972. Thank You.

Sincerely,

K. Paul Thadikonda, PhD
President & CEO

[redacted]

[redacted]

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

3 April 2003

Subject: [redacted] Clinical Study # CLO-0199

Dear Dr. Thadikonda:

The cover letter dated March 13, 2001 which accompanied our shipment to you of [redacted] for use in the CLO-0199 clinical study referred to [redacted] Lot #019011. Its attached Certificate of Analysis and Request for Clinical Trial Material Supplies (RCTMS) form also referred to Lot #019011. The manufacturing lot number for the batch was 019011.

[redacted]

However, when that batch was packaged there were 4 packaging configurations. [redacted] SOPs provide that an alpha character is appended to the end of the manufacturing lot number to differentiate each of the various packaging configurations (A, B, C, etc.). Of the four [redacted] configurations, three were in bottles. The one for the clinical study was unique in its configuration of cartons of [redacted] each. The [redacted] were contained in foil packet strips of ten (4 strips per carton). The lot number for the clinical study packaging configuration was 019011A.

While the cover letter and RCTMS did not include the "A" with the lot number, the RCTMS did clearly describe the "A" configuration of cartons of [redacted] each. Further, the outer label indicated Lot # 019011A.

The Certificate of Analysis (COA) is correct in having the Production Lot # 019011 as it covers the entire manufactured lot of 300,000 [redacted], and COAs are not specific to the various packaging configurations.

[redacted]

Please be assured that [redacted] is confident that we and Eminent Services adhered to all appropriate GMP and GCP regulations regarding the packaging and labeling of the clinical supplies for CLO-0199, and that we believe the documentation is both reasonable and adequate.

Sincerely,

[redacted]

cc: [redacted]
Associate Director
[redacted]