Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13110

8 - OTHER

This form should be filled out at the time of the Adverse Drug Experience (ADE). Please complete this form and place the copy in the Pharmacy order bin within 24 hours.

[redacted]

Date of ADE: _____ Adversity Occurred: ☐ in House ☒ on Admission

Diagnosis(es): respiratory failure, seizures

Known Allergies: _____

Suspected Drug(s): mahuang (herbal containing ephedrine), guara

Other Concomitant Drugs: _____

Relevant Laboratory Values: _____

**Description of ADE** (circle appropriate observations):

| | |
|---|---|
| *Cardiovascular:* | Angina, Arrhythmia, CHF, Hypertension, Hypotension, Shock, Palpitations, Syncope |
| *CNS:* | Anxiety, Depression, Drowsiness, Extrapyramidal, Hallucinations, Headache, Insomnia, Pain, Tinnitus, Vertigo |
| *Dermatologic:* | Rash, Itch, Hives, Flushing, Perspiration |
| *Gastrointestinal:* | Nausea, Vomiting, Diarrhea, Constipation, Anorexia. Jaundice, Hematemesis, Cramping, Dry Mouth |
| *Genitourinary:* | Altered Renal Status, Hematuria, Difficulty Voiding |
| *Respiratory:* | Bronchospasm, Depression, Cough |

Other: seizures, resp. failure, cardiomyopathy.

Physician Notified: Dr [redacted] aware Date/Time: 7/3/98

Was Drug Discontinued? ☒ YES ☐ NO _____ Patient Rechallenged? NO

If NO, reason _____

Action Taken: valium, vered for seizures

[redacted]

000002

WHITE - Chart YELLOW - Pharmacy

[redacted]

Adverse Drug Experience Reporting Form

[redacted]

**CLINICAL SUMMARY**
**08/21/98**

Unit Number: [redacted] Name: [redacted]

Account Number: [redacted] Discharge Date: 07/15/98 10:08

Attending Phys: [redacted]

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DRG : 475 RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT
MLOS : 8.2000
HCFA Weight : 3.7291

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**Diagnoses**

* [redacted]
RESPIRATORY FAILURE
PRIMARY CARDIOMYOPATHIES
PNEUMONITIS DUE TO INHALATION OF FOOD OR VOMITUS
CARDIOGENIC SHOCK
STAPHYLOCOCCAL SEPTICEMIA
CONVULSIONS
CANDIDIASIS OF UROGENITAL SITE
POISONING BY DIETETIC
DISORDER OF MUSCLE/LIGAMENT/FASCIA
HYPOPOTASSEMIA
OBESITY, UNSPECIFIED

| Procedures | Date | Surgeon |
|---|---|---|
| * [redacted] CONTINUOUS MECHANICAL VENTILATION FOR | 07/03/98 | [redacted] |
| LEFT HEART CARDIAC CATHETERIZATION | 07/03/98 | |
| FIBER-OPTIC BRONCHOSCOPY | 07/05/98 | |
| FIBER-OPTIC BRONCHOSCOPY | 07/11/98 | |

18/21

Coder: [redacted]

[redacted]

CLINICAL SUMMARY
11/25/98

[redacted]

Unit Number: [redacted] Name: [redacted]

Account Number: [redacted] Discharge Date: 07/15/98 10:08

Attending Phys: [redacted]

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DRG : 475 RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT
MLOS : 8.2000
HCFA Weight : 3.7291

---

**Diagnoses**

* [redacted]
RESPIRATORY FAILURE
PRIMARY CARDIOMYOPATHIES
PNEUMONITIS DUE TO INHALATION OF FOOD OR VOMITUS
CARDIOGENIC SHOCK
STAPHYLOCOCCAL SEPTICEMIA
CONVULSIONS
CANDIDIASIS OF UROGENITAL SITE
POISONING BY DIETETIC
ACCIDENTAL POISONING FROM POISONOUS PLANT
DISORDER OF MUSCLE/LIGAMENT/FASCIA
HYPOPOTASSEMIA
OBESITY, UNSPECIFIED

| Procedures | Date | Surgeon |
|---|---|---|
| * [redacted] CONTINUOUS MECHANICAL VENTILATION FOR | 07/03/98 | [redacted] |
| LEFT HEART CARDIAC CATHETERIZATION | 07/03/98 | |
| FIBER-OPTIC BRONCHOSCOPY | 07/05/98 | |
| FIBER-OPTIC BRONCHOSCOPY | 07/11/98 | |

Retransmitted
Added E Code

Coder: [redacted]
Date Billed:11/25/98

[redacted]

Thu Jul 16, 1998 12:06 am
Discharge Cumulative Trend Report from 07/03/98 1320 to 07/15/98 0910

Patient Name: [redacted] Notification-Page 2
Med Rec #: Adm: 07/03/98
Dis Date 07/15/98
Phys-Service: [redacted] *NEUROLOGY

**********

LABORATORY CANCELLED AND SPECIMEN REJECTED TESTS

****SPECIMEN CANCELLED****

Accn: [redacted] Acct: [redacted]
Spec: Blood Collected: 07/04/98 0600
Priority: NEXT AM RND MICU Ord Phys: [redacted]

Test Name: CARBON DIOXIDE

Cancelled: 07/04/98 0612
Cancellation Reason: DUPLICATE ORDER

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****SPECIMEN CANCELLED****

Accn: [redacted] Acct: [redacted]
Spec: Blood Collected: 07/04/98 0600
Priority: TIME MICU Ord Phys: [redacted]

Test Name: CK + CKMB
MAGNESIUM

Cancelled: 07/04/98 2034
Cancellation Reason: DUPLICATE ORDER

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****SPECIMEN CANCELLED****

Accn: [redacted] Acct: [redacted]
Spec: Blood Collected: 07/04/98 0600
Priority: TIME MICU Ord Phys: [redacted]

Test Name: PROTEIN TOTAL

Cancelled: 07/04/98 0612
Cancellation Reason: DUPLICATE ORDER

---

****SPECIMEN CANCELLED****

Accn: [redacted] Acct: [redacted]
Spec: Blood Collected: 07/05/98 0500
Priority: STAT Ord Phys: [redacted]

Test Name: MAGNESIUM
CHEM12 (COMPREHENSIVE)

Cancelled: 07/05/98 0630
Cancellation Reason: ORDERED IN ERROR

---

End of Report

[redacted]

Lab Director- [redacted] M.D.
** DO NOT DISCARD **
*Discharge Cumulative Trend Report

[redacted]

[redacted]

Thu Jul 16, 1998 12:06 am

Discharge Cum Incomplete Work Listing from 07/03/98 1320 to 07/15/98 0910

Patient Name: [redacted] Page 1

Med Rec #: [redacted] Adm: 07/03/98

Dis Date 07/15/98

Phys-Service: [redacted] *NEUROLOGY

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| Accession Number | Test Name | Spec Type | Collection Date & Time | Status |
|---|---|---|---|---|
| [redacted] | CULTURE BLOOD | Blood BC Ca | 07/05/98 0135 | Partial |
| | CULTURE BLOOD | Blood BC | 07/05/98 0140 | Partial |
| | EBV AB IGG/IGM BY IFA | Blood | 07/09/98 0155 | Sendout |
| | CMV AB IGM | Blood | 07/09/98 0155 | Sendout |
| | ENTEROVIRUS AB PANEL | Blood | 07/09/98 0155 | Sendout |
| | CULTURE URINE | Urine Midst | 07/15/98 0910 | Spec Rec |

End of Report

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Lab Director- [redacted]

** DO NOT DISCARD **

*Discharge Cum Incomplete Work Listing

[redacted]

[redacted]

[redacted]

Thu Jul 16, 1998 12:06 am

Discharge Cumulative Trend Report from 07/03/98 1320 to 07/15/98 0910

Patient Name: [redacted] BLOOD BANK-Page 23

Med Rec #: Adm: 07/03/98

Dis Date

Phys-Service: [redacted]*NEUROLOGY

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Blood Bank Panel

| Results:<br>Units:<br>LO:<br>HI: | ABO/Rh | Du | Ab Sc | Ab ID | DAT | Ag Scr | X-Match |
|---|---|---|---|---|---|---|---|
| 07/06/98 0817 | A POS | | NEG | | | | 1 |
| 07/06/98 0817 | | | | | | | 2 |

Lab Director- [redacted] M.D.

** DO NOT DISCARD **

*Discharge Cumulative Trend Report

[redacted]