TLC Trial Form ADE.04
Adverse Drug Experience Case Report Form

Send to:
TLC Data Coordinating Center

INSTRUCTIONS: This form is to be filled out when there has been a serious and unexpected adverse drug experience. For the purposes of the TLC Trial, any event which results in inpatient hospitalization or death during the treatment phase is considered a serious and unexpected adverse drug experience, even if thought to be unrelated to study drug. The TLC Form ADECHK, documenting reporting procedures, should also be filled out. If this ADE was immediately life-threatening or resulted in death, the TLC physician must notify the FDA by phone within three working days.

BACKGROUND INFORMATION
1. Gender ( ), Boy ( ), Girl
2. Date of Birth _____ _____ / _____ _____ / _____ mm/dd/yy

ADVERSE EXPERIENCE
3. Case report status ( ), New case ( ), Follow-up report
4. Date of onset _____ _____ / _____ _____ / _____ mm/dd/yy
5. Inpatient hospitalization ( ), No ( ), Yes
   a. Date admitted _____ _____ / _____ _____ / _____ mm/dd/yy
   b. Date discharged _____ _____ / _____ _____ / _____ mm/dd/yy ( ), Still in hospital as of this report
   c. Hospital Name of hospital
      Address
      City State and Zip
6. Date resolved _____ _____ / _____ _____ / _____ mm/dd/yy ( ), Unresolved as of this report
7. Life threatening ( ), No ( ), Yes
8. Fatal ( ), No ( ), Yes
   a. Date of death _____ _____ / _____ _____ / _____ mm/dd/yy

If this ADE was life-threatening or fatal, the TLC physician must notify the FDA by phone within the next three working days.

9. Describe the events surrounding this ADE. Record all pertinent details, including concomitant medications, intercurrent events, and duration if less than 24 hours.

If this ADE was immediately life-threatening or resulted in death, the TLC physician must notify the FDA by phone within three working days.
### STUDY DRUG

10. **Treatment status**
    - ( ), Round 1
    - ( ), Round 2
    - ( ), Round 3
    - ( ), Followup

*If this child was in treatment phase at time of this event:*

11. **Date started drug**
    - _____ _____ / _____ _____ / _____ mm/dd/yy

12. **Dosage**
   - a. Days 1 to 7
      - _____ - _____
   - b. Days 8 to 26
      - _____

13. **Date stopped drug**
    - _____ _____ / _____ _____ / _____ mm/dd/yy
    - ( ), Still taking study drug

14. **As a result of this ADE, were any changes made in the administration of TLC Study drug?**
    - ( ), No change in administration of Study drug
    - ( ), Study drug discontinued permanently
    - ( ), Study drug interrupted and restarted
    - ( ), Other, specify:

### OUTCOME

15. **In the opinion of the TLC physician, was this ADE related to TLC Study drug?**
    - ( ), Related
    - ( ), Possibly related
    - ( ), Not related
    - ( ), Not known

16. **Was this ADE the result of overdose?**
    - ( ), No
    - ( ), Yes

17. **Was this ADE permanently disabling?**
    - ( ), No
    - ( ), Yes

18. **Has this child suffered any permanent damage as a result of this ADE?**
    - ( ), No
    - ( ), Yes

19. **Did this child require prolonged hospitalization as a result of this ADE?**
    - ( ), No
    - ( ), Yes

20. **Did this ADE cause cancer?**
    - ( ), No
    - ( ), Yes

### ADMINISTRATIVE MATTERS

21. **Date**
    - _____ _____ / _____ _____ / _____ mm/dd/yy

22. **TLC Physician**
    - Signature
    - TLC code

### COMMENTS

For DCC use only

( ), Succimer ( ), Placebo

IND #: 45,248
Sponsor: NIEHS
Drug name: Chemet (succimer)
Treatment of Lead-exposed Children Trial

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