

Start Time : 19-AUG-2008 12:37:54

Database : NRG46B

User ID : BGALLIEN

# Oracle AERS

Queue ID : 21

## CIOMS I (Draft)

Report Parameter	Value
Case ID?	1999GOLD0056
As of time?	19-AUG-2008 12:37:54
Case Version Statuses?	C,D,R
Local As Of Rule?	G
Draft/Submission/Reprint (D/S/R)?	D
Agency/Country (use code(s) or a list)	\$CIOMSI_AGENCIES
Print box 7+13 details?	Y
Print Seriousness Other?	Y
Print Reporter Info?	Y
Print Risk Assessment?	C
Suppress reporter name/address if reporter is patient?	Y
Print Blinded Data?	N
Identify Co Added Term (**)?	N
Suppress printing signs and symptoms in Cioms I form?	N
Report Form?	15 DAY CIOMS
Modification Reason Code?	SR
Manufacturer Name?	Oracle
Manufacturer Address 1?	Oracle
Manufacturer Address 2?	200 Oracle Parkway
Manufacturer Address 3?	Redwood Shores, CA 94065 USA
Print suspect drug dosing details?	Y
Print clinical trials details to support EU CTD?	N
Include causality assessment in narrative generation?	N
Use lower level terms (LLT) instead of preferred terms?	N

Report Parameter	Value
Generate event details?	Y
Generate additional narrative(Test comment, lab tests, etc)?	Y
Consolidate Event Terms	Y
Keep report data in temporary tables?	Y
Report Format?	PDF
Enter TimeZone for printing the Report	America/Los_Angeles
Enter language code	en
Pick From Dose Closest Record	N
Derivation Logic for Box 24D:	CL
Use follow-up date in box 24c?	Y
Print both Initial and Most Recent Received Dates in Box G4?	N

Case ID List
1999GOLD0056

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) QQQ	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year 01 JUN 1951	2a. AGE 52 YEARS	3. SEX FEMALE	4-6. REACTION ONSET Day Month Year 20 JUN 2003	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input checked="" type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION  <input type="checkbox"/> INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING  <input type="checkbox"/> CONGENITAL ANOMALY  <input checked="" type="checkbox"/> OTHER: TERST
7+ 13 DESCRIBE REACTION(S) [Including relevant tests/lab data. reporter/COMPANY VERBATIM (Coded Term). **=Company Added/Reclassified] stomach ache (Abdominal pain upper) Unknown cotton wool in head (Feeling abnormal) Unknown overdose (Overdose) Unknown  Consumer reports abdominal pain afterTaKing saspirin. And he is found dead now. this is a new letter  Lab Tests:  <div>Cont.</div>						

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) ( include generic name) TEST COMPANY NAME (NO PREF. NAME) Dose, form, route and frequency Unknown		Therapy Dates Unknown		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO  <input type="checkbox"/> UNKNOWN <input type="checkbox"/> NA
15. DAILY DOSE Unknown	16. ROUTE(S) OF ADMINISTRATION Unknown			21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO  <input type="checkbox"/> UNKNOWN <input type="checkbox"/> NA
17. INDICATION(S) FOR USE Unknown				
18. THERAPY DATES (FROM/TO) Unknown		19. THERAPY DURATION Unknown		

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (Exclude those used to treat reaction) SASPIRIN (SUPER SALICYLIC ACID) (Con.) 01JAN2003:20JUN2003	
23. OTHER RELEVANT HISTORY (e.g diagnosis, allergies, pregnancy with last month of period etc.) headache Unknown	

IV. MANUFACTURER INFORMATION

V. INITIAL REPORTER (IN CONFIDENCE)

24a. NAME AND ADDRESS OF MANUFACTURER PARENT COMPANY Oracle 200 Oracle Parkway Redwood Shores, CA 94065 USA		26-26A. NAME AND ADDRESS OF REPORTER ( INCLUDE ZIP CODE ) CONTACT56
LICENSE DETAILS	24b. MFR. CONTROL NO. 1999GOLD0056	
24c. DATE RECEIVED BY MANUFACTURER 09NOV2003	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> REGULATORY AUTHORITY	
DATE OF THIS REPORT 19AUG2008	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP	

Page 1 of 2

**SUSPECT ADVERSE REACTION REPORT Continued**

Oracle - Manufacturer Control No: 1999GOLD0056

7+13. DESCRIBE REACTION(S) (Including relevant tests/lab data) (Continued)					
Test Name	Coll. Date	Result	Unit	Low Value	High Value
cbc	01AUG1994	UNK	UNK	UNK	UNK
CBC	01AUG1994	100	MG	UNK	UNK

User ID : BGALLIEN

# Oracle AERS

Database : NRG46B

Queue ID : 21

## CIOMS I (Draft)-Trailer Page

### Totals :

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Total Cases	1
Total Valid Cases	1
Total Invalid Cases	0

### Error Messages

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No messages