Appendix C

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
JSW	US				20 Months	M	13	NOV	1992

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Accidental overdose (therapeutic agent)

A PHYSICIAN REPORTED AN ACCIDENTAL OVERDOSE WITH PRAVASTATIN 20 MG INVOLVING A 20 MONTH OLD MALE PATIENT. ON NOVEMBER 13, 1992 THE MOTHER OF THE PATIENT REPORTED THAT SHE HAD FOUND ONE PRAVASTATIN TABLET IN HER SON'S MOUTH. SHE "SUSPECTS THAT TWO TABLETS MAY HAVE BEEN INGESTED." THE PHYSICIAN STATES THAT THE CHILD DID NOT HAVE ANY SYMPTOMS OR SEQUELAE. THE PHYSICIAN STATED THAT THE CHILD DID NOT EXPERIENCE ANY ADVERSE EVENT AS A RESULT OF THE OVERDOSE.

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVACHOL TABS (pravastatin sodium)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

15.DOSE(S)

#1 20 Milligram

16.ROUTE OF ADMINISTRATION

#1 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

18. THERAPY DATES(from/to)

#1 13NOV1992-13NOV1992

19. THERAPY DURATION

#1 1 Day

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 NONE (none)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
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Mail Location HW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO

M028192

24c. DATE RECEIVED BY MANUFACTURER

09FEB1993

24d REPORT SOURCE

☐ Study ☐ Literature ☐ Other

☒ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
MT	US				0	F	07	SEP	1995

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Accidental overdose (therapeutic agent)

A PHARMACIST SPONTANEOUSLY REPORTED THAT A FEMALE PATIENT IN HER 60'S HAD ACCIDENTLY TAKEN AN OVERDOSE OF EIGHT TABLETS OF THE "NEW" FORMULATION OF PRAVACHOL (PRAVASTATIN SODIUM) 20 MG FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA. THE REPORTER INDICATED THAT ON SEPTEMBER 7, 1995, THE PATIENT WAS TO TAKE ONE TABLET OF PRAVASTATIN SODIUM DAILY AND EIGHT TABLETS OF PREDNISONE. THE PATIENTS SON WAS EXPECTED TO VISIT AND THE PATIENT BECAME EXCITED AND CONFUSED AND TOOK EIGHT PRAVASTATIN SODIUM TABLETS AND ONE PREDNISONE TABLET. AS OF SEPTEMBER 8, 1995, THE PATIENT HAS NOT EXPERIENCED AN ADVERSE EVENT, INCLUDING ANY ABDOMINAL DISCOMFORT, FROM TAKING THE EIGHT PRAVASTATIN SODIUM TABLETS. THE REPORTER ALERTED THE PATIENT'S PHYSICIAN AND THE PATIENT WAS INSTRUCTED TO REPORT ANY COMPLAINTS TO HER PHYSICIAN. FOLLOW-UP INFORMATION RECEIVED ON SEPTEMBER 27, 1995, INDICATED THAT THE PATIENT, BORN IN 1918, HAD A MEDICAL HISTORY OF ALLERGIES TO GRASS, RAGWEED, POTATOES AND WHEAT CHARACTERIZED BY ATOPIC
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVACHOL TABS 20 MG (pravastatin sodium)

15.DOSE(S)

#1 20 Milligram

16.ROUTE OF ADMINISTRATION

#1 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia

18. THERAPY DATES(from/to)

#1

19. THERAPY DURATION

#1

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 PREDNISONE (prednisone) 07SEP1995-UNK

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 "ALLERGIC TO GRASS"-NOT CODED #2 "ALLERGY RAGWEED"-NOT CODED #3 "ALLERGY TO WHEAT"-NOT CODED #4 "ALLERGY POTATOES"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
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Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO

M052870

24c. DATE RECEIVED BY MANUFACTURER

27SEP1995

24d REPORT SOURCE

☐ Study ☐ Literature ☐ Other

☒ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							07	SEP	1995

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

DERMATITIS. THE LOT NUMBER REPORTED WAS 65J12A, EXPIRATION DATE 7/98 AND NDC # 00003-5178-05. NO ADVERSE EVENT WAS REPORTED AS A RESULT OF THE OVERDOSE.

LAB DATA: #1 NONE- X

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
M052870

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	US				0	F		SEP	1998	

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Accidental overdose (therapeutic agent)

A PHARMACIST SPONTANEOUSLY REPORTED THAT A FEMALE PATIENT (AGE WAS NOT REPORTED) ACCIDENTLY OVERDOSED, WHICH REQUIRED ADMISSION TO THE HOSPITAL, WHILE TAKING PRAVACHOL (PRAVASTATIN SODIUM) TABLET THERAPY. PRAVACHOL THERAPY, 10 MG AT BEDTIME, WAS TAKEN FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA. IN SEPTEMBER 1998, THE PATIENT TOOK 10 TABLETS (100 MG TOTAL) OF PRAVACHOL IN THE MORNING AND IN THE EVENING FOR 6 DAYS. IT WAS REPORTED "THIS WAS NOT INTENTIONAL; IT WAS ACCIDENTAL." PRAVACHOL THERAPY WAS DISCONTINUED. THE PATIENT WAS ADMITTED TO THE HOSPITAL. AS OF SEPTEMBER 15, 1998, THE PATIENT IS OUT OF THE HOSPITAL, "FEELING FINE" AND IS EATING. LIVER FUNCTION TESTS, CREATINE PHOSPHOKINASE (CPK), CREATININE, BLOOD UREA NITROGEN (BUN) AND URINALYSIS WERE NEGATIVE. FURTHER INFORMATION HAS BEEN REQUESTED.

LAB DATA: #1 LFT'S- Normal, #2 CPK- Normal, #3 CREATININE- Normal, #4 BUN- Normal, #5 URINALYSIS- Normal

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVACHOL TABS 10 MG (pravastatin sodium)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 10 Milligram	#1 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 UNK-00SEP1998	#1

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 NOT REPORTED (unknown to us)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 "NOT REPORTED"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

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24b MFR CONTROL NO

M086918

24c. DATE RECEIVED BY MANUFACTURER

15SEP1998

24d REPORT SOURCE

☐ Study ☐ Literature ☐ Other

☒ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
J	GB-1772 LIPOSTA				0	F	27	APR	1995

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Accidental overdose (therapeutic agent)

A FEMALE CONSUMER REPORTED THAT SHE ACCIDENTLY TOOK AN "OVERDOSE" OF LIPOSTAT TABLETS (PRAVASTATIN SODIUM) 10 MG FOR HYPERCHOLESTEROLEMIA. THE PATIENT HAD TAKEN HER 10 MG DOSE OF LIPOSTAT THERAPY THE NIGHT OF APRIL 26, 1995. THE NEXT MORNING, APRIL 27, 1995, SHE HAD TAKEN AN ADDITIONAL TABLET OF LIPOSTAT. SHE REPORTED THAT SHE DID NOT EXPERIENCE AN ADVERSE EVENT DUE TO TAKING THE ADDITIONAL TABLET.

LAB DATA: #1 NOT REPORTED

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 LIPOSTAT TABS 10 MG (pravastatin sodium)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

15.DOSE(S)

#1 10 Milligram

16.ROUTE OF ADMINISTRATION

#1 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na

☐ yes ☐ no ☐ na

18. THERAPY DATES(from/to)

#1 27APR1995-27APR1995

19. THERAPY DURATION

#1 1 CONTINUOUS

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 NOT REPORTED (unknown to us)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 "NOT REPORTED"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

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24b MFR CONTROL NO

B021414

24c. DATE RECEIVED BY MANUFACTURER

27APR1995

24d REPORT SOURCE

☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
HG	NL-96094	10	JUL	1960	56 Years	M	09	AUG	1996

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Non-accidental overdose, #2 Suicide attempt

A PHYSICIAN SPONTANEOUSLY REPORTED THAT A 56 YEAR OLD MALE PATIENT ATTEMPTED SUICIDE BY OVERDOSING ON SELEKTINE (PRAVASTATIN SODIUM), SELOKEEN (METOPROLOL) AND ACETYLSALICYLIC ACID TABLETS. PRAVASTATIN SODIUM THERAPY, 20 MG DAILY, WAS INITIATED IN NOVEMBER 1995 FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA. THE PATIENT WAS ALSO TAKING METOPROLOL, 100 MG DAILY, AND ACETYLSALICYLIC ACID, 80 MG DAILY STATUS POST MYOCARDIAL INFARCTION. THE PATIENT ATTEMPTED SUICIDE ON AUGUST 9, 1996 BY SWALLOWING 52 PRAVASTATIN 20 MG TABLETS (TOTAL=1.04 GRAMS), 90 METOPROLOL 100 MG TABLETS (TOTAL=9 GRAMS), AND 46 ACETYLSALICYLIC ACID 80 MG TABLETS (TOTAL=3.64 GRAMS). PRIOR TO SWALLOWING THE PILLS, THE PATIENT DRANK SIX TO TEN UNITS OF ALCOHOL. THE PHYSICIAN REPORTED THAT AFTER TAKING THE PILLS, THERE WERE NO SYMPTOMS AND THE PATIENT WAS FEELING WELL. THE PATIENT WAS ADMITTED TO THE HOSPITAL FIVE HOURS AFTER THE EVENT AND IMMEDIATELY WAS TREATED WITH A STOMACH LAVAGE. AT NIGHT, THERE WERE NO CARDIAC
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 SELEKTINE TABS 20 MG (pravastatin sodium)

#2 SELOKEEN (metoprolol tartrate)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☒ yes ☐ no ☐ na

#2 ☒ yes ☐ no ☐ na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 52	#1 ORAL
#2 90	#2 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia

#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na

#2 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 09AUG1996-UNK	#1
#2 09AUG1996-UNK	#2 (Continued)

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 NOT REPORTED (unknown to us)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 "STATUS POST MYOCARDIAL INFARCTION"-NOT CODED #2 Alcoholism

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

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United States

24b MFR CONTROL NO

B028411

24c. DATE RECEIVED BY MANUFACTURER

23SEP1996

24d REPORT SOURCE

☐ Study ☐ Literature ☐ Other

☒ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							09	AUG	1996

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

ABNORMALITIES SUCH AS BRADYCARDIA OR AV PROBLEMS. NO PSYCHOPATHOLOGY WAS PRESENT. WHILE IN THE HOSPITAL, THE PATIENT WAS WELL AND THERE WERE NO CARDIAC OR PULMONARY ABNORMALITIES PRESENT. BLOOD PRESSURE WAS 110/70 MMHG. ELECTROCARDIOGRAM SHOWED SIGNS OF THE OLD INFARCTION AND NOTED NO PR PROLONGATION AND SINUS BRADYCARDIA WAS 55. LABORATORY VALUES WERE NORMAL EXCEPT FOR ALANINE AMINOTRANSFERASE (ALAT) 41 U/L (NORMAL: 5 TO 40 U/L) ON AUGUST 9, 1996, ALKALINE PHOSPHATASE 136 U/L (NORMAL: 30 TO 125 U/L) AND 126 U/L ON AUGUST 9, 1996 AND AUGUST 13, 1996 RESPECTIVELY. PRAVASTATIN SODIUM AND METOPROLOL THERAPIES WERE BOTH DISCONTINUED. ACCORDING TO THE REPORTER, "THERE WERE CLEAR EXTERNAL FACTORS LEADING TO THE SUICIDE, THERE WAS NO RELATION BETWEEN THE CHRONIC TREATMENT AND THE SUICIDE ATTEMPT". THE PATIENT RECOVERED WITHOUT LASTING SYMPTOMS OR DAMAGE.

(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#3 ACETYLSALICYLIC ACID
#4 ALCOHOL (ethyl alcohol)

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#3 46	#3 ORAL
#4	#4 ORAL

20. DID REACTION ABATE AFTER STOPPING DRUG?

#3 ☒ yes ☐ no ☐ na
#4 ☒ yes ☐ no ☐ na

17.INDICATION(S) FOR USE

#3 "STATUS POST MYOCARDIAL INFARCTION"-NOT CODED
#4

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#3 09AUG1996-UNK	#3
#4 09AUG1996-UNK	#4

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#3 ☐ yes ☐ no ☒ na
#4 ☐ yes ☐ no ☒ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B028411

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
							09	AUG	1996

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

FOLLOW-UP INFORMATION WAS RECEIVED ON SEPTEMBER 23, 1996. IT WAS REPORTED THE PATIENT EXPERIENCED A MYOCARDIAL INFARCTION AND WAS ADMITTED TO THE HOSPITAL ON OCTOBER 30, 1995 AND DISCHARGED IN NOVEMBER 1995. ON JANUARY 11, 1996, PRAVASTATIN SODIUM THERAPY, 20 MG DAILY WAS INITIATED AND NOT ON NOVEMBER 1, 1995 AS ORIGINALLY REPORTED. PRAVASTATIN SODIUM THERAPY WAS INCREASED TO 40 MG DAILY ON MARCH 18, 1996.

LAB DATA: #1 CREATINE KINASE-09AUG1996 98 U/L Normal, #2 CREATINE KINASE-09AUG1996 92 U/L Normal, #3 CREATINE KINASE-13AUG1996 79 U/L Normal, #4 CREATINE KINASE-19AUG1996 90 U/L Normal, #5 CREATINE KINASE-20AUG1996 68 U/L Normal, #6 ALAT-09AUG1996 41 U/L Abnormal, #7 ALAT-09AUG1996 30 U/L Normal, #8 ALAT-13AUG1996 38 U/L Normal, #9 ALAT-16AUG1996 37 U/L Normal, #10 ALAT-20AUG1996 37 U/L Normal, #11 ASAT-09AUG1996 27 U/L Normal, #12 ASAT-13AUG1996 32 U/L Normal, #13 ASAT-16AUG1996 31
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐yes ☐no ☐na ☐yes ☐no ☐na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐yes ☐no ☐na ☐yes ☐no ☐na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergies,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B028411

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							09	AUG	1996

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

U/L Normal, #14 ASAT-20AUG1996 30 U/L Normal, #15 ASAT-23AUG1996 29 U/L Normal, #16 ALKALINE PHOSPHATASE-09AUG1996 136 U/L Abnormal, #17 ALKALINE PHOSPHATASE-09AUG1996 107 U/L Normal, #18 ALKALINE PHOSPHATASE-13AUG1996 126 U/L Abnormal, #19 ALKALINE PHOSPHATASE-16AUG1996 124 U/L Normal, #20 ALKALINE PHOSPHATASE-20AUG1996 120 U/L Normal, #21 BLOOD PRESSURE- 110/70 MMHG

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐yes ☐no ☐na
☐yes ☐no ☐na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐yes ☐no ☐na
☐yes ☐no ☐na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B028411

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
	FR-ELI/19970698				37 Years	M	25	SEP	1997

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Suicide attempt, #2 Non-accidental overdose, #3 Blood creatine phosphokinase increased

THIS IS A REPORT RECEIVED FROM THE FRENCH PHARMACOVIGILANCE OF FRANCE (FILE #PS9700643). A PHYSICIAN REPORTED THAT A 37 YEAR OLD MALE PATIENT ATTEMPTED SUICIDE TAKING ELISOR (PRAVASTATIN SODIUM), LASILIX (FUROSEMIDE) AND DI-ANTALVIC (DEXTROPROPOXYPHENE, PARACETAMOL). THE PATIENT TOOK 280 MG OF ELISOR, 800 MG OF LASILIX AND DI-ANTALVIC (DOSAGE WAS NOT REPORTED) ON SEPTEMBER 25, 1997. CREATINE PHOSPHOKINASE (CPK) WAS NOTED TO BE 265 (NORMAL: LESS THAN 200) ON SEPTEMBER 25, 1997. THE PATIENT WAS ADMITTED TO THE HOSPITAL. A GASTRIC LAVAGE WAS PERFORMED AND A TREATMENT WITH CHARBON + FLUIMICIL (ACETYLCYSTEINE) WAS GIVEN. CPK WAS NOTED TO BE 48 ON SEPTEMBER 29, 1997.

LAB DATA: #1 NOT REPORTED

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 ELISOR TABS (pravastatin sodium)
#2 LASILIX (furosemide)

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 280 Milligram	#1 ORAL
#2 800 Milligram	#2

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☒ yes ☐ no ☐ na
#2 ☒ yes ☐ no ☐ na

17.INDICATION(S) FOR USE

#1
#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 25SEP1997-25SEP1997	#1 1 Day
#2 25SEP1997-25SEP1997	#2 1 Day (Continued)

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 NOT REPORTED (unknown to us)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 "NOT REPORTED"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
Mail Location HW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO: B035760

24c. DATE RECEIVED BY MANUFACTURER: 01DEC1997

24d REPORT SOURCE: ☐ Study ☐ Literature ☐ Other ☒ Health Professional

25. DATE OF THIS REPORT: 29SEP1999

25a REPORT TYPE: ☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							25	SEP	1997

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)
#3 DI-ANTALVIC (propoxyphene hcl + apap)

20. DID REACTION ABATE AFTER STOPPING DRUG?
#3 ☒ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

15.DOSE(S)
#3

16.ROUTE OF ADMINISTRATION
#3

17.INDICATION(S) FOR USE
#3

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#3 ☐ yes ☐ no ☒ na
☐ yes ☐ no ☐ na

18. THERAPY DATES(from/to)
#3 25SEP1997-25SEP1997

19. THERAPY DURATION
#3 1 Day

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B035760

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
RY	FR				57 Years	F	27	FEB	1990

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Overdose NOS, #2 Suicide attempt

PATIENT INTENTIONALLY ATTEMPTED AN OVERDOSE BY INGESTING 14 PRAVASTATIN TABLETS AND VERALIPRID TABLETS. SIX HOURS LATER A GASTRIC LAVAGE WAS PERFORMED. THE PATIENT DID NOT EXPERIENCE ANY CLINICAL SYMPTOMATOLOGY. LABDATA: HEMOGRAM: NORMAL; CPK: 30 UL/L; LDH: 263 UL/L; SGOT: 22 UL/L; SGPT: 22 UL/L; GGT: 22 UL/L; PAL: 76 UL/L; AMYLASEMIA: 64 UL/L; CHOLESTEROL: 2.49 G/L; TRIGLYCERIDE: 1.54 G/L.

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVASTATIN SODIUM
#2 VERALIPRIDE

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 14	#1 ORAL
#2	#2

17.INDICATION(S) FOR USE

#1 "SUICIDE-DRUG/MEDICIN NEC"-NOT CODED
#2 "SUICIDE-DRUG/MEDICIN NEC"-NOT CODED

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1	#1
#2	#2

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 ANAFRANIL (clomipramine)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 Depression NEC

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

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United States

24b MFR CONTROL NO
B006907

24c. DATE RECEIVED BY MANUFACTURER
05MAR1990

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☒ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							09	MAR	1994

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(Include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#3 CHLORPHENAMINE (chlorpheniramine maleate)
#4 ASCORBIC ACID (ascorbic acid)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergies,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B016782

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
VA	FR-CAP/19981072				59 Years	M	07	NOV	1998

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Overdose NOS, #2 Death NOS, #3 Completed suicide, #4 Cardio-respiratory arrest

A PHYSICIAN, FROM AN ANTIPOISONING CENTER REPORTED A SUSPECTED OVERDOSAGE WITH SEVERAL MEDICATIONS POSSIBLY INCLUDING LOPRIL (CAPTOPRIL). THE FEMALE PATIENT CONSEQUENTLY DIED.

ADDITIONAL INFORMATION RECEIVED ON NOVEMBER 26, 1998, FROM THE PHYSICIAN, INDICATED THAT THIS WAS A MALE PATIENT. THE PATIENT HAD TAKEN AN OVERDOSE OF THE FOLLOWING MEDICATIONS: 30 TABLETS OF AMLOR (AMLODIPINE), 30 TABLETS OF VASTEN (PRAVASTATIN), 30 TABLETS OF LOPRIL (CAPTOPRIL), 40 120 MG TABLETS OF ISOPTINE (VERAPAMIL), AND ALCOHOL. UPON ARRIVAL TO THE HOSPITAL EMERGENCY ROOM, THE PATIENT WAS STILL CONSCIOUS AND HIS ARTERIAL PRESSURE WAS "STILL ALRIGHT". DURING TRANSPORTATION, HIS BLOOD PRESSURE FELL DRAMATICALLY. THE PATIENT WAS INTUBATED AND VENTILATED AFTER HIS SYSTOLIC BLOOD PRESSURE REACHED 5 MMHG AND HIS HEART RATE FELL TO 35 BPM AND 20 BPM.
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- [x] LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 LOPRIL TABS (captopril)
#2 AMLOR (amlodipine besylate)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 [ ] yes [ ] no [x] na
#2 [ ] yes [ ] no [x] na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 30	#1 ORAL
#2 30	#2 ORAL

17.INDICATION(S) FOR USE

#1
#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 [ ] yes [ ] no [x] na
#2 [ ] yes [ ] no [x] na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 UNK-07NOV1998	#1
#2 UNK-07NOV1998	#2 (Continued)

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

#1 Angina pectoris #2 Myocardial infarction #3 Depression NEC

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
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P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO

B042920

24c. DATE RECEIVED BY MANUFACTURER

23DEC1998

24d REPORT SOURCE

[ ] Study [ ] Literature [ ] Other
[x] Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

[x] Initial [ ] Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							07	NOV	1998

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

HE RECEIVED INOTROPIC MEDICATIONS (ISUPREL (ISOPRENALINE), ADRENALIN, GASTRIC LAVAGE WITH ACTIVATED CHARCOAL AND GLUCAGON. HE DIED OF CARDIORESPIRATORY ARREST 6 HOURS AFTER HIS ARRIVAL AND DURING INPUT OF A PACE-MAKER.

ADDITIONAL INFORMATION RECEIVED ON DECEMBER 23, 1998, INDICATED THAT THIS PATIENT'S HISTORY INCLUDED DEPRESSION. THE FRANCE LOCAL HEALTH AUTHORITIES NUMBER FOR THIS REPORT IS PA9838350, AND THE "RPR-SPECIA" REFERENCE NUMBER IS FR0110310.

LAB DATA: #1 BLOOD PRESSURE SYSTOLIC- 5 MMHG , #2 HEART RATE- 35 BPM , #3 HEART RATE- 20 BPM

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(Include generic name)

#3 VASTEN (pravastatin sodium)
#4 ISOPTIN (verapamil hcl)

20. DID REACTION ABATE AFTER STOPPING DRUG?

#3 ☐ yes ☐ no ☒ na
#4 ☐ yes ☐ no ☒ na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#3 30	#3 ORAL
#4 40	#4 ORAL

17.INDICATION(S) FOR USE

#3
#4

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#3 ☐ yes ☐ no ☒ na
#4 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#3 UNK-07NOV1998	#3
#4 UNK-07NOV1998	#4

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B042920

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
FRA229138 0002-27	FR				59 Years	M	12	MAY	1993

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

#1 Accidental overdose (therapeutic agent)

OUR AFFILIATE FROM FRANCE REPORTED THAT A 59-YEAR OLD WHITE MALE INADVERTENTLY INGESTED THE INCORRECT DAILY DOSAGE OF STUDY DRUG WHILE PARTICIPATING IN A DOUBLE BLIND PHASE IV (22-91038) CLINICAL TRIAL WITH PRAVACHOL (PRAVASTATIN)/ PLACEBO FROM MAY 12, 1993 TO JUNE 17, 1993. THE PATIENT HAD TAKEN STUDY MEDICATION 20 MG FOUR TIMES A DAY INSTEAD OF TWICE A DAY AS PRESCRIBED. NO OTHER EVENTS WERE NOTED. HE REINITIATED STUDY DRUG THERAPY ON JULY 19, 1993. CONCOMITANT MEDICATION INCLUDES ASPEGIC AND FONZYLANE. MEDICAL HISTORY INCLUDES A PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY ON MAY 11, 1993

LAB DATA: #1 NOT REPORTED

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVACHOL TABS 20 MG (pravastatin sodium)
#2 PLACEBO

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 20 Milligram	#1 ORAL
#2	#2 ORAL

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia
#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 12MAY1993-17JUN1993	#1 5 Week
#2	#2

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 ASPEGIC (aspirin) 11MAY1993-UNK
#2 FONZYLANE (buflomedil hcl) 11MAY1993-UNK

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

Race: Caucasian.
#1 "PTCA"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
Mail Location HW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO

B015763

24c. DATE RECEIVED BY MANUFACTURER

03DEC1993

24d REPORT SOURCE

☒ Study ☐ Literature ☐ Other
☒ Health Professional

25. DATE OF THIS REPORT

29SEP1999

25a REPORT TYPE

☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
PRA049702 -1148	AU	06	APR	1944		M	15	APR	1999

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

#1 Hypotension NOS, #2 Bradycardia NOS, #3 Accidental overdose (therapeutic agent)

A CLINICAL INVESTIGATOR REPORTED THAT A 55 YEAR OLD MALE WAS ADMITTED TO THE HOSPITAL WITH HYPOTENSION, BRADYCARDIA, AND AN ACCIDENTAL OVERDOSE OF IMDUR (ISOSORBIDE MONONITRATE) WHILE PARTICIPATING IN A BLINDED CLINICAL STUDY WITH PRAVASTATIN SODIUM. THE EVENTS OCCURRED ON THE SEVENTEENTH DAY OF THERAPY WITH STUDY MEDICATION. CONCOMITANT MEDICATIONS, ATENOLOL AND IMDUR, WERE CONSIDERED SUSPECT. THE PATIENT WAS MONITORED FOR 48 HOURS. ATENOLOL WAS DISCONTINUED AND THE DOSAGE OF IMDUR WAS REDUCED TO THE PRESCRIBED DOSE. THE EVENTS RESOLVED.

PROTOCOL #PRA04/97.002 ENTITLED: PACT: PRAVASTATIN ACUTE CORONARY TREATMENT

INVESTIGATOR CAUSALITY: NOT RELATED TO STUDY MEDICATION.

BMS MEDICAL MONITOR CASUALITY: NOT RELATED TO STUDY MEDICATION.

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(Include generic name)

#1 PRAVASTATIN SODIUM
#2 IMDUR (isosorbide mononitrate)

15.DOSE(S)	16.ROUTE OF ADMINISTRATION	20. DID REACTION ABATE AFTER STOPPING DRUG?
#1 20 Milligram	#1 ORAL	#1 ☐ yes ☐ no ☒ na
#2	#2	#2 ☐ yes ☐ no ☒ na

17.INDICATION(S) FOR USE		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1		#1 ☐ yes ☐ no ☒ na
#2		#2 ☐ yes ☐ no ☒ na
18. THERAPY DATES(from/to)	19. THERAPY DURATION	
#1 30MAR1999-28APR1999	#1	
#2 05APR1999-UNK	#2 (Continued)	

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 ASPIRIN (aspirin) 30MAR1999-UNK

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergies,pregnancy with last month of period,etc.)

Race: Other.

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

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United States

24b MFR CONTROL NO: 10100592

24c. DATE RECEIVED BY MANUFACTURER: 20MAY1999

24d REPORT SOURCE: ☒ Study ☐ Literature ☐ Other ☒ Health Professional

25. DATE OF THIS REPORT: 29SEP1999

25a REPORT TYPE: ☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
							15	APR	1999

6-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)
#3 ATENOLOL

20. DID REACTION ABATE AFTER STOPPING DRUG?
#3 ☐ yes ☐ no ☒ na
☐ yes ☐ no ☐ na

15.DOSE(S)
#3

16.ROUTE OF ADMINISTRATION
#3

17.INDICATION(S) FOR USE
#3

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#3 ☐ yes ☐ no ☒ na
☐ yes ☐ no ☐ na

18. THERAPY DATES(from/to)
#3 30MAR1999-15APR1999

19. THERAPY DURATION
#3

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
10100592

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
PRA229138 0012-20	FR				67 Years	M	12	SEP	1993

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

#1 Blood creatine phosphokinase increased, #2 Overdose NOS

AN INVESTIGATOR REPORTED THAT A 67 YEAR OLD CAUCASIAN MALE PATIENT PARTICIPATED IN A BLINDED STUDY "PREDICT: PREVENTION OF RESTENOSIS WITH PRAVASTATIN AFTER TRANS LUMINAL CORONARY DILATION" (PRA/22-91.038). THE PATIENT RECEIVED PRAVACHOL (PRAVASTATIN) 40 MG DAILY OR A PLACEBO FOR NINE MONTHS FOR HYPERCHOLESTEROLEMIA AND EXPERIENCED AN INCREASED CPK LEVEL DUE TO AN ERROR IN DOSING (OVERDOSE). THE INVESTIGATOR INDICATED THAT THE PATIENT RECEIVED 144 TABLETS BETWEEN VISITS TWO AND FOUR FOR 48 DAYS AND ANOTHER 144 TABLETS BETWEEN VISITS FOUR AND SIX FOR 65 DAYS. THE PATIENT'S CPK LEVEL WAS TESTED FOR FIVE CONSECUTIVE TESTS BETWEEN VISITS TWO AND SIX, AND ON ALL OCCASSIONS, THE CPK LEVEL REPORTEDLY WAS INCREASED. THE PATIENT WAS ASYMPTOMATIC AND THE EVENT REPORTEDLY RESOLVED. CONCOMITANT MEDICATIONS INCLUDE ACEPROMAZINE MALEATE 10 MG, NICERGOLINE 15 MG AND PERIDAMOL 4 MG. THE INVESTIGATOR DID NOT ATTRIBUTE THE EVENT TO THE STUDY MEDICATION.
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVACHOL TABS (pravastatin sodium)
#2 PLACEBO

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 40 Milligram	#1 ORAL
#2	#2 ORAL

20. DID REACTION ABATE AFTER STOPPING DRUG?

#1 ☒ yes ☐ no ☐ na
#2 ☒ yes ☐ no ☐ na

17.INDICATION(S) FOR USE

#1 Hypercholesterolaemia
#2 Hypercholesterolaemia

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 10JUL1993-30MAR1994	#1 9 Month CONTINUOUS
#2	#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 ACEPROMAZINE MALEATE (acepromazine maleate)
#2 NICERGOLINE (nicergoline)
#3 PERINDOPRIL (perindopril)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

Race: Caucasian.
#1 "TRANSLUMINAL CORONARY DILATION"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
Mail Location BW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO
B018873

24c. DATE RECEIVED BY MANUFACTURER
27SEP1994

24d REPORT SOURCE
☒ Study ☐ Literature ☐ Other
☒ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							12	SEP	1993

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

LAB DATA: #1 CPK-09DEC1993 54 UI/L , #2 CPK-30MAR1993 271 UI/L

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ yes ☐ no ☐ na
☐ yes ☐ no ☐ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B018873

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
PRA229138 0012-21	FR				53 Years	M	09	FEB	1994

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Overdose NOS

IT WAS REPORTED THAT A 53-YEAR-OLD WHITE MALE TOOK AN OVERDOSAGE OF STUDY MEDICATION WHILE PARTICIPATING IN DOUBLE-BLIND PHASE IV CLINICAL TRIAL IN THE "PREVENTION OF RESTENOSIS WITH ELISOR (PRAVASTATIN) AFTER TRANSLUMINAL CORONARY DILATION." THE PATIENT INITIATED PRAVASTATIN 20 MG DAILY OR PLACEBO ON OCTOBER 8, 1993. CONCOMITANT MEDICATIONS INCLUDED SOTALOL, NITRIDERM, ACETYLSALICYLIC ACID, TICLOPIDINE, AND RAMIPRIL. IT WAS REPORTED THAT THE PATIENT INGESTED 144 TABLETS OF STUDY DRUG OVER A PERIOD OF FIFTY-ONE DAYS, (FROM FEBRUARY 9, 1994 TO APRIL 1, 1994). NO ADVERSE EVENT WAS REPORTED TO HAVE OCCURRED. THE INVESTIGATOR DID NOT ATTRIBUTE THE EVENT TO STUDY DRUG THERAPY.

LAB DATA: #1 NOT REPORTED

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 ELISOR TABS (pravastatin sodium)
#2 PLACEBO

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1	#1 ORAL
#2	#2 ORAL

20. DID REACTION ABATE AFTER STOPPING DRUG?
#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

17.INDICATION(S) FOR USE

#1 Coronary artery disease NOS
#2

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 08OCT1993-01APR1994	#1 6 Month
#2 08OCT1993-01APR1994	#2 6 Month

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 SOTALOL (sotalol hcl)
#2 NITRODERM (nitroglycerin)
(Continued)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

Race: Caucasian.
#1 "PTCA"-NOT CODED

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
Mail Location HW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO
B019261

24c. DATE RECEIVED BY MANUFACTURER
02NOV1994

24d REPORT SOURCE
☒ Study ☐ Literature ☐ Other
☒ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
							09	FEB	1994

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

6-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐yes ☐no ☐na ☐yes ☐no ☐na

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐yes ☐no ☐na ☐yes ☐no ☐na

18. THERAPY DATES(from/to)

19. THERAPY DURATION

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#3 ACETYLSALICYLIC ACID (acetylsalicylic acid)
#4 TICLOPIDINE (ticlopidine hcl) 12OCT1993-UNK
#5 RAMIPRIL (ramipril) 10OCT1993-UNK

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B019261

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
PRA049702 0-564	AU	13	JUN	1953	45 Years	M	30	OCT	1998

7+13 DESCRIBE REACTION(S)(including relevant tests/lab data)

#1 Angina pectoris, #2 Overdose NOS

AN INVESTIGATOR REPORTED THAT A 45 YEAR OLD MALE EXPERIENCED POST-CORONARY ANGINA WHILE PARTICIPATING IN THE BLINDED PHASE OF A PRAVASTATIN SODIUM STUDY. PRAVASTATIN THERAPY, 20 MG ORALLY DAILY, WAS INITIATED ON OCTOBER 30, 1998. THE EVENT OCCURRED ON OCTOBER 30, 1998, AND WAS CONSIDERED TO BE A MEDICALLY SIGNIFICANT EVENT. THE PATIENT'S CREATINE KINASE-M BAND (CK-MB) ON OCTOBER 30 WAS 198 U/L. HIS CREATINE KINASE (CK) ON OCTOBER 31 WAS 911 U/L AND WAS 219 U/L ON NOVEMBER 1. THE PATIENT WAS TREATED WITH OXYGEN, MORPHINE, AND ANGININE. THE EVENT RESOLVED ON NOVEMBER 2. PRAVACHOL THERAPY WAS DISCONTINUED ON NOVEMBER 26, 1998.

TITLE OF STUDY: PACT-PRAVASTATIN ACUTE CORONARY TREATMENT PROGRAM

INVESTIGATOR CAUSALITY: NOT RELATED TO STUDY MEDICATION.
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

#1 PRAVASTATIN SODIUM
#2 ATENOLOL

15.DOSE(S)	16.ROUTE OF ADMINISTRATION
#1 20 Milligram	#1 ORAL
#2	#2

20. DID REACTION ABATE AFTER STOPPING DRUG?
#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

17.INDICATION(S) FOR USE
#1
#2

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1 ☐ yes ☐ no ☒ na
#2 ☐ yes ☐ no ☒ na

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1 30OCT1998-26NOV1998	#1
#2 03NOV1998-UNK	#2

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#1 HEPARIN (heparin) 30OCT1998-02NOV1998
#2 ASPIRIN (aspirin) 30OCT1998-UNK
(Continued)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

Race: Other.
#1 Depression NEC

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

Murray Barnhart
Bristol-Myers Squibb Company
Worldwide Safety & Surveillance
Mail Location HW19-1.01
P.O. Box 5400
Princeton, NJ 08543-5400
United States

24b MFR CONTROL NO
B046237

24c. DATE RECEIVED BY MANUFACTURER
31AUG1999

24d REPORT SOURCE
☒ Study ☐ Literature ☐ Other
☒ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☒ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-5.REACTION ONSET Day	Month	Year
							30	OCT	1998

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

BMS CAUSALITY: NOT RELATED TO STUDY MEDICATION.

SUPPLEMENTAL INFORMATION RECEIVED 16NOV98 INDICATED THAT ON THE 18TH DAY OF THERAPY WITH STUDY MEDICATION, THE PATIENT WAS ADMITTED TO THE HOSPITAL WITH BETA BLOCKADE POISONING. CONCOMITANT MEDICATION ATENOLOL WAS CONSIDERED SUSPECT. THE EVENT RESOLVED WITH NO TREATMENT. STUDY MEDICATION WAS CONTINUED.

INVESTIGATOR CASUALITY: NOT RELATED TO STUDY MEDICATION.

BMS MEDICAL MONITOR CAUSALITY: NOT RELATED TO STUDY MEDICATION.

SUPPLEMENTAL INFORMATION RECEIVED 31AUG99 CLARIFIED THE REPORTED TERM "BETA BLOCKADE POISONING". THE INVESTIGATOR CHANGED THE REPORTED TERM OF "BETA BLOCKADE POISONING"
(Continued)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐yes ☐no ☐na ☐yes ☐no ☐na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐yes ☐no ☐na ☐yes ☐no ☐na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

#3 METOPROLOL (metoprolol tartrate) 31OCT1998-03NOV1998
#4 ZOLOFT (sertraline hcl) 31OCT1998-UNK

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B046237

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup

Bristol-Myers Squibb Company
Pharmaceutical Research Institute

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT ID	1.a COUNTRY	2.DATE OF BIRTH Day	Month	Year	2.a AGE	3.SEX	4-6.REACTION ONSET Day	Month	Year
							30	OCT	1998

7+13 DESCRIBE REACTION(S)(Including relevant tests/lab data)

TO "OVERDOSE." ADDITIONAL INFORMATION HAS BEEN REQUESTED. THE CAUSALITY ASSESSMENT REMAINS UNCHANGED.

SUPPLEMENTAL INFORMATION RECEIVED 01SEP99 INDICATED THAT THE PATIENT TOOK AN OVERDOSE OF ATENOLOL. THE OVERDOSING WAS ATTRIBUTED TO THE PATIENT'S UNDERLYING DEPRESSION.

LAB DATA: #1 CK-MB-30OCT1998 198 U/L , #2 CREATINE KINASE-31OCT1998 911 IU/L , #3 CREATINE KINASE-01NOV1998 219 IU/L

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II.SUSPECT DRUG(S) INFORMATION

14.SUSPECT DRUG(S)(Include generic name)

15.DOSE(S)

16.ROUTE OF ADMINISTRATION

17.INDICATION(S) FOR USE

18. THERAPY DATES(from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?

☐ yes ☐ no ☐ na

☐ yes ☐ no ☐ na

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

☐ yes ☐ no ☐ na

☐ yes ☐ no ☐ na

III.CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION(exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY(e.g.diagnostics,allergics,pregnancy with last month of period,etc.)

IV. MANUFACTURER INFORMATION

24.a NAME AND ADDRESS OF MANUFACTURER

24b MFR CONTROL NO
B046237

24c. DATE RECEIVED BY MANUFACTURER

24d REPORT SOURCE
☐ Study ☐ Literature ☐ Other
☐ Health Professional

25. DATE OF THIS REPORT
29SEP1999

25a REPORT TYPE
☐ Initial ☐ Followup