



APPENDIX VI

Total number of pages = 34

**Adverse Events**

Data Collection Form 5A

Subject Initials SML Subject # 1

Study No. 03-122085-106

Page No. IV-227

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
red bumps	7-25-03	8/7/03	N	1	1	1	4	<i>[Signature]</i> 8-16-03	
Entry Date	Comment/Note: Possible due to test organism E-LJ 8/16-03								Initials
7/28/03	red bumps on hands								gn
8/7/03	stated that hand and fingers are clear, unwilling to return to lab for follow up check.								gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
see above for dates			8/5/03	gn					
Entry Date	Comment/Note:								Initials
7-29-02	Four pink papules on hand and fingers								E-LJ

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials MGB Subject # 3

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/25/03	8/4/03	N	1	1	1	4	<i>[Signature]</i> 8/16/03 Initials
Entry Date	Comment/Note: Probably due to test organism							
7/25/03	red bumps on both hands and wrists							
8/4/03	hands clear. no medications used							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials LEB Subject # 4

Study No. 03-122085-106

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Reaction to Effexor	6/9/03	7/3/03	N	1	1	1	4	<i>[Signature]</i> 8-10-03
Entry Date	Comment/Note:							Initials
8/6/03	Took 225mg effexor for anxiety 1x day from 6/9/03 to 7/3/03, discontinued use due to neurological problems							gru

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials LMP Subject # 6

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>Papules</i>	<i>7-25-03</i>	<i>8/7/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>4</i>	<i>E. Levin</i>
Entry Date	Comment/Note:							Initials
<i>7-29-03</i>	<i>Probably due to test organism E. faecalis</i>							<i>E.L.</i>
	<i>Three red papules on backs of hand and fingers.</i>							<i>7-29-03</i>
<i>8/7/03</i>	<i>Hands + fingers clear no medications used</i>							<i>EL</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials ELG Subject # 12

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/25/03	8/11/03	N	1			4	<i>[Signature]</i> 8-16-03
Entry Date	Comment/Note: Probably due to lost organism							
7/28/03	red bumps on right and left hand.							
8/11/03	Hand cleans used cortisone 10 and mesopaine 2 times on 7/28/03 and 8/1/03							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates	8/11/03							
Entry Date	Comment/Note:							
7-29-03	Three red papules on backs of hands.							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials C.R.N. Subject # 15

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	7-30-03	8/8/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: <i>Used Non-Rx Cortisone (2) Due to lost organism</i>							
8-4-03	Four red macules on the backs of the hands							
8/8/03	Hands clear - used cortisone .05mg 1 time on 7/31/03							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials VLW Subject # 18

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps	7/24/03	8/14/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: ① Used Non-Rx: Neosporin (z) Due to test organism							
7/25/03	red bumps on both hands and wrists							
	right seven bumps, left 3 bumps							
8/14/03	Hands + wrists clear - neosporin							
	used at night from 7/24/03 - 8/13/03 as needed.							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials G A H Subject # 24

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Pink areas	8-10-03	8/11/03	N	1	1	1	4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: * Probably due to test organism - <i>[Signature]</i> 8-21-03							Initials
8-4-03	Two pink areas on backs of hands.							<i>[Signature]</i>
8/11/03	Hands clear no medications used							<i>[Signature]</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials AKG Subject # 29

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ADVERSE EVENTS

*E. J. ...*

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/23/03	8/21/03	N	L	1	5	4*	<i>E. J. ...</i> 8-21-03
Entry Date	Comment/Note: *Probably due to test organism.							Initials
7/25/03	red bumps on right and left hands and wrists.							gn
8/21/03	Subject contacted on 8.5.03, 8.7.03 and 8.11.03 without response							gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe  
 Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated  
 Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)  
 Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience  
5 = Test to follow up

Data Collection Form 5A

Subject Initials E.M. Mc Subject # 31

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Macules	8/1/03	8/12/03	H	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03	
Entry Date	Comment/Note: Discontinuation of Neosporin (2) Due to lost organism								Initials
8-4-03	Seven red macules on the backs of the hands								<i>[Signature]</i> 8-21-03
8/12/03	Hands clear - neosporin used on bumps on from 8/4/03 to 8/10/03 1 to 2 times a day.								<i>[Signature]</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials W.A.A. Subject # 34

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ADVERSE EVENTS

*E.L.J.*

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
<i>Macules</i>	<i>7-30-03</i>	<i>9/14/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>41</i>	<i>4*</i>	<i>E.L.J. 8-21-03</i>
Entry Date	Comment/Note: <i>* Probably due to test organism E.L.J. 8-21-03</i>							Initials
<i>8-4-03</i>	<i>Seven red macules on the backs of the hands</i>							<i>E.L.J.</i>
<i>9/14/03</i>	<i>Hands clear no medications used</i>							<i>gh</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity:           1=Mild                                   2=Moderate                                   3=Severe
- Relationship:   1=Definite                               2=Probable                               3=Possible                               4=Unrelated
- Action Taken:   1=None                                       2=Rx Therapy                               3=Discontinued Study               4=Other (specify)
- Outcome:        1=Resolved w/o sequelae               2=Resolved w/ sequelae (describe)   3=Ongoing                               4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials MTP Subject # 35

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 ③ 8.11.03 gr

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
red bumps	7/23/03	7/28/03	N	1			4*	<i>[Signature]</i> 8-24-03	
Entry Date	Comment/Note: * Probably due to test organism E. coli								Initials
7/25/03	red bumps on both forearms								gr
7/23/03	Spands clear no medications used								gr

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials MLP Subject # 37

Study No. 03-122085-106

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
<i>Popules</i>	<i>7-25-03</i>	<i>8/13/03</i>	<i>N</i>	<i>1</i>	<i>4(1)</i>	<i>1</i>	<i>4(2)</i>	<i>[Signature]</i>	
Entry Date	Comment/Note:								Initials
<i>7-29-03</i>	<i>1) Used Non-Rx Neosporin 2) Due to test response</i>								<i>[Initials]</i>
<i>8/13/03</i>	<i>Three popules on wrists</i>								<i>[Initials]</i>
	<i>Used neosporin occasionally - hands &amp; wrists clear, forearms &amp; wrist clear</i>								
	<i>neosporin used from 7/29/03 - 8/12/03 as needed</i>								

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials BGR Subject # 38

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ADVERSE EVENTS

*E.J. Jimenez*

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps w/ swelling	8/1/03	8/21/03	N	1	1	5	4*	<i>E.J. Jimenez</i> 8-21-03
Entry Date	Comment/Note: * Probably due to test organism.							Initials
8/1/03	red bumps with swelling on left hand							<i>gn</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for events & dates 8/21/03 <i>gn</i>								
Entry Date	Comment/Note:							Initials
8-4-03	Four red woules on the backs of the hands							<i>E.J. Jimenez</i>
8/21/03	Subject contacted on 8.7.03 and 8.11.03 without response							<i>gn</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience  
5 = Test to follow up

Data Collection Form 5A

Subject Initials D.A.B Subject # 39

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Cellulitis	7-31-03	8/13/03	N	2	2	1	4*	E.F.J. 8-21-03	
Entry Date	Comment/Note: * Probably due to test organism - E.F.J.								Initials
7-31-03	Swelling on back of right hand around a puslath								E.F.J. 8-21-03
8/13/03	took 500mg tylenol 4x on 7/31/03								
8/13/03	hands + forearms clear								gjn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Mocules	see above for dates						8/13/03	gjn	
Entry Date	Comment/Note:								Initials
8-4-03	Three red mocules on hands and forearms.								E.F.J.
8/13/03	went to Dr. Jones office and was prescribed 500mg #20 cephalexin 1x day for 10 days								

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials RK B Subject # 42

Study No. 03-122085-106

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>Macules</i>	<i>8-4-03</i>	<i>8/2/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>4X</i>	<i>E. J. [Signature]</i>
Entry Date	Comment/Note: <i>* Probably due to test organism - E. J. [Signature]</i>							Initials
<i>8-4-03</i>	<i>One red macule on the right wrist</i>							<i>8-21-03</i>
<i>8/3/03</i>	<i>Wrist clear no medications used</i>							<i>gn</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials √JC Subject # 43

Study No. 03-122085-106  
Page No. IV-456

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>Papules</u>	<u>7-27-03</u>	<u>8/1/03</u>	<u>N</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>4*</u>	<u>[Signature]</u> <u>8-21-03</u>
Entry Date	Comment/Note: <u>* Probably due to test organism. 8-21-03</u>							Initials
<u>7-28-03</u>	<u>Three red papules on the wrists and forearms.</u>							<u>[Signature]</u>
<u>8/1/03</u>	<u>Hands &amp; wrist clear - no medications used</u>							<u>[Signature]</u>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials BAG Subject # 44

Study No. 03-122085-106  
Page No. IV-462

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps with itching	7/24/03	8/15/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: 1) Used Non Rx cortisone cream → Due to local exposure							Initials
7/25/03	red bumps with itching on both hands							gn
8/15/03	Cortisone cream used 2 times on							gn
	7/28/03. Hands clear							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates				8/15/03				gn
Entry Date	Comment/Note: Has used cortisone cream.							Initials
								<i>[Signature]</i> 7-28-03

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials TLR Subject # 48

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Page No. IV-483

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bump	7/31/03	8/4/03	X	1			4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: *Probably due to lost organism.							Initials
8/1/03	red bump on left hand							gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates				8/4/03				gn
Entry Date	Comment/Note:							Initials
8-4-03	Hands are clear today							<i>[Signature]</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials WTS Subject # 51

Study No. 03-122085-106

Page No. IV-499

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps w/itching	7/23/03	7/29/03	N	1	4(1)	1	4(2)	E. J. [Signature]
Entry Date	Comment/Note: 1) Used Hum H. Hydrocortisone cream - 2) Due to lot of [unclear] Initials							
7/25/03	red bumps and itching on both hands gnu							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
see above for dates	7/28/03	gnu						
Entry Date	Comment/Note:							
7-28-03	Clear today used hydrocortisone cream E. J. [Signature]							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials LDI Subject # 55

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Page No. IV-519a

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
cold	7/31/03	8/12/03	N	1			4	<i>[Signature]</i> 8/12/03
Entry Date	Comment/Note:							Initials
8/7/03	stuffy nose and chest congestion taking tylenol cold medication OTC 4x day started on 8/1/03							gr
8/12/03	ended medication on 8/11/03, all clear on 8/12/03							gr

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials KAL Subject # 56

Study No. 03-122085-106

Page No. IV-524a

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Headache	8/2/03	8/21/03	N	2	2	5	4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: * Unrelated illness.							Initials
8/4/03	Headache, cough, chest pain, and sinus. Took 500mg amoxicillin on 8/2/03.							gn
8/7/03	Dr Jones prescribed 500mg of amoxicillin for 5 days 1 tablet per day. - symptoms persist							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates				8/7/03	gn			
Entry Date	Comment/Note:							Initials
8/7/03	but feeling better.							gn
8/21/03	Subject contacted on 8.7.03 and 8.11.03 without response							gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience  
5 = Lost to follow up

Subject Initials I-G Subject # 57

Study No. 03-122085-106

Page No. IV-53D

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
red bumps	7/30/03	8/4/03	N	1			4X	E. T. J. 8-21-03	
Entry Date	Comment/Note: * Probably due to test organism, E.T.J.								Initials
8/1/03	red bumps w/ itching on hands								gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
All above for dates		8/4/03						gn	
Entry Date	Comment/Note:								Initials
8-4-03	Hands are clear today.								E. T. J.

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials JWO Subject # 60

Study No. 03-122085-106

Page No. II-546

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps w/itching	7/30/03	8/11/03	N	1			4*	<i>E-J</i> 8-21-03 gn
Entry Date	Comment/Note: * Probably due to lost organisms, <i>E-J</i> 8-21-03 gn							
7/31/03	red bumps with itching on both hands subject plans to use bacitracin on hands for three days							
8/11/03	hand clears <sup>①</sup> 8.11.03 gn							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
	see above for dates			3				<i>E-J</i> 8-7-03 gn
Entry Date	Comment/Note:							
8-4-03	Three red macules on the dorsa of the hands <i>E-J</i>							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials R.L.M. Subject # 01

Study No. 03-122085-106

Page No. IV-552

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>Pustule</u>	<u>7-31-03</u>	<u>8/2/03</u>	<u>N</u>	<u>1</u>	<u>4 (1)</u>	<u>1</u>	<u>4 (2)</u>	<u>[Signature]</u> 8/2/03
Entry Date	Comment/Note: 1) Used Non-Rx Neosporin 2) Ducts for organisms							
<u>8-4-03</u>	<u>One pustule on forearm and three red macules on the backs of the hands</u>							
<u>8/2/03</u>	<u>Hands and forearm clear</u>							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>see above</u>	<u>for dates</u>			<u>8/12/03</u>		<u>gr</u>		
Entry Date	Comment/Note:							
<u>8/12/03</u>	<u>neosporin used on bumps from 8/4/03 to 8/10/03 1 to 2 times a day</u>							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials C.A.B. Subject # 64

Study No. 03-122085-106

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>Papules</i>	<i>7-31/03</i>	<i>8/14/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>4*</i>	<i>E. J. J. 8-21-03</i>
Entry Date	Comment/Notes: <i>* Probably due to test organism. E. J. J.</i>							Initials
<i>8-4-03</i>	<i>Six red papules on the hands and forearms</i>							<i>E. J. J.</i>
<i>8/14/03</i>	<i>Hands &amp; forearms clear no medications used</i>							<i>E. J. J.</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials DMH Subject # 70

Study No. 03-122085-106  
Page No. IV-599

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>bumps</i>	<i>7/31/03</i>	<i>8/21/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>5</i>	<i>4*</i>	<i>[Signature]</i> <i>8-21-03</i>
Entry Date	Comment/Note: <i>* Probably due to test organism.</i>							Initials
<i>8/1/03</i>	<i>red bumps on fingers with soreness</i>							<i>gh</i>
<i>8/21/03</i>	<i>Subject contacted on 8-7-03 and 8-11-03 without response</i>							<i>gh</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<i>see above for dates 8.7.03 gh</i>								
Entry Date	Comment/Note:							Initials
<i>8-4-03</i>	<i>Two papules on the back of the left hand</i>							<i>[Signature]</i>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience *5= Int to follow up*

Data Collection Form 5A

Subject Initials JTF Subject # 71

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Page No. IV-605

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps/swelling	7/29/03	8/7/03	N	1	1	1	4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: *Probable due to test organism E.L.J. as reported by subject by phone conversation							
7/31/03	red bumps on both hands with itching and swelling. added 8-21-03 gr							
8/7/03	hands and wrist clear - no medications used gr							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates	8.7.03							gr
Entry Date	Comment/Note:							
8-4-03	Two papules on the left wrist E.L.J.							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe  
 Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated  
 Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)  
 Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials CCS Subject # 72

Study No. 03-122085-106

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/31/03	8/11/03	N	1			4*	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: * I probably due to test organism. @ L.G.							Initials
8/1/03	red bumps on right & left hands							gn
8/4/03	cold w/ head & chest congestion							gn
8/7/03	cold clear							gn
8/11/03	Hands clear no medications used							gn

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Macules	see above for dates							
Entry Date	Comment/Note:							Initials
8-4-03	Four red macules on left hand and forearm.							E.T.G.

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials S-W Subject # 73

Study No. 03-122085-106  
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③  
8.6.03  
gn

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
rash on wrist	7/31/03	8/7/03	N	1	4(1)	1	4(2)	E. J. (8-21-03) gn
Entry Date	Comment/Note: 1) Used Abn of cortisone 2) Due to test organism							
8/1/03	red rash on wrist with itching 8-21-03 gn							
8/7/03	hands & forearms cream - used gn							
	cortisone-10 2 to 3 times a day from 7/31/03 to 8/7/03							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Popules	see above for dates						gn	
Entry Date	Comment/Note:							
8-4-03	Three red popules on forearm. E. J. D. gn							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Subject Initials EJB Subject # 77

Study No. 03-122085-106  
Page No. IV-638

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7/29/03	8/6/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03 gr
Entry Date	Comment/Note: 1) Used topical cortisone 10 2) Due to test organism							
7/31/03	red bumps on right hand.							
8/6/03	hands clear - used cortisone 10 2 times a day from 7/31/03 to 8/3/03							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above	for dates	8/5/03						gr
Entry Date	Comment/Note:							
8-1-03	Four pink macules on the backs of the hands							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials E.L.J. Subject # 80

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Page No. IV-654

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
<u>Popule</u>		<u>8/13/03</u>	<u>N</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>4*</u>	<u>E.L.J. 8-21-03</u>
Entry Date	Comment/Note: <u>* Probably due to test organism E.L.J.</u>							Initials
<u>8-1-03</u>	<u>One papule on the back of the left hand.</u>							<u>E.L.J.</u>
<u>8/13/03</u>	<u>Hand clear no medications used</u>							<u>gk</u>

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe  
 Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated  
 Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)  
 Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials SAS Subject # 82

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
red bumps	7-29/03	8/5/03	N	1	1	1	4*	E. J. J. 8-21-03
Entry Date	Comment/Note: * Probably due to test organism E. J. J. 8-21-03							
7/30/03	red bumps on left hand and wrist							
8/5/03	hands clear - no medications used.							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
see above for dates				8/5/03				gh
Entry Date	Comment/Note:							
8-14-03	Three pink maculae on back of left hand							

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience

Data Collection Form 5A

Subject Initials M. F. M. Subject # 89

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ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Macules	7-31-03	8/11/03	H	1			4*	<i>[Signature]</i> 8/21/03	
Entry Date	Comment/Note: * Probably due to test organism. E.F.J.								Initials
8-4-03	Five red macules on forearms. 8-24-03 E.F.J.								
8/11/03	Hands clear and no medications used. ga								

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Symptom / Event	Onset Date	End Date	SAE <sup>1</sup> Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

- Severity: 1=Mild 2=Moderate 3=Severe
- Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated
- Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)
- Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

<sup>1</sup>Serious Adverse Event/Experience