

TABLE 1 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CH591	3625	111001	(b) (6)	03/24/92	BUMP RIGHT ARM (SITE OF ALLERGY SHOT)
	CH595	3315	111001	(b) (6)	03/06/92	DAY 11, 21 AND 36 DOSE 1, ROOT CANAL-DENTIST
					03/16/92	
					03/30/92	

TABLE 1 (CONT.)

Post-Vaccination Reactions in Healthy Children and Adolescents Reported to CBER

Study #	Case #	BB-IND	Lot of Vaccine	PFU/Dose	Date Vaccine Administered	Date of Event	Date Reported	Summary of Event	Vaccine* Related
974	(b) (6)	375	C-R647	1625	07/25/88	09/05/88	10/28/88	A 13-month-old female (Case (b) (6)) was vaccinated on 7/25/88. On 9/5/88 she entered the hospital for elective bilateral inguinal hernia surgery. She was released on 9/7/88 and has recovered. The investigator believes this experience was unrelated to vaccination.	No
974	(b) (6)	375	C-R724	1460	01/12/89	01/27/89	05/25/89	A 9-year-old male (Case (b) (6)) was hospitalized 17 days after vaccination for reactive airway disease. The patient was treated and released 4 days later recovered. The investigator does not consider this experience related to the study vaccine.	No
975	(b) (6)	375	CR452	1140	04/06/89	04/12/89	07/6/89	Case (b) (6) was hospitalized 6 days after vaccination for gastroenteritis, RSV pneumonia and bilateral otitis media. He was discharged 6 days after admission. The investigator believes the case to be non-related to vaccination.	No

*Clinical investigator's assessment.

XPROJECT.1690

300CT92

4-00690

TABLE 37 (cont.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CR647	54	099201	(b) (6)	01/22/89	MOTHER WAS WITH CHILDREN ON THE 22ND AND THEY GOT CHICKEN-POX ON JANUARY 29TH (I ALREADY HAD THEM AS A CHILD) - CHILD NOT EXPOSED ONLY MOM.
			099201	(b) (6)	03/02/89	DAY 1, FLATUS.
	162		099201	(b) (6)	02/20/89	DAY 26 - SMALL TRACE OF BLOOD ON RECTUM AFTER BOWEL MOVEMENT. NO BLOOD VISIBLE IN STOOL, HOWEVER.
	542		099201	(b) (6)	03/16/89	DAYS 36-40 FEVER BLISTER ON LIP
					03/17/89	
					03/18/89	
					03/19/89	
					03/20/89	
	1625		099201	(b) (6)	03/04/89	

TABLE 27

Multicenter Study
 Serious Adverse Experiences in Healthy Adolescents and Adults

<u>Study No.</u>	<u>Case No.</u>	<u>BB-IND</u>	<u>Lot Vaccine</u>	<u>PFU/Dose</u>	<u>Date Vaccine Administered</u>	<u>Date of Event</u>	<u>Date Reported</u>	<u>Summary of Event</u>	<u>Vaccine Related</u>
1038	(b) (6)	375	C-T683	1230	3/22/91	5/6/91	5/22/91	This 25 year-old male received the first dose of varicella vaccine on 3/22/91. On 5/6/91 he was admitted to the hospital with abdominal pain and nausea until 5/8/91 when he was discharged after observation only. He received the second injection of Oka/Merck vaccine on 5/21/91, and reported no further complaints.	Definitely Not
1030	(b) (6)	375	C-T684	905	12/20/90	12/26/90	1/22/91	This 26 year-old female was vaccinated with varicella vaccine on 12/20/90. On 12/22/90 she developed flu-like symptoms, including aching muscles and fever. She developed further symptoms including liver enlargement and was admitted to the hospital on 12/26/90 with a diagnosis of pericarditis and pleural effusion. Viral culture from aspirate was nonconclusive. The patient was discharged on 1/4/91; by 1/3/91 the effusion was resolved.	Definitely Not

XINFWPC.795/91

30APR93

TABLE 27 (CONT.)

Multicenter Study
 Serious Adverse Experiences in Healthy Adolescents and Adults

<u>Study No.</u>	<u>Case No.</u>	<u>BB-IND</u>	<u>Lot Vaccine</u>	<u>PFU/Dose</u>	<u>Date Vaccine Administered</u>	<u>Date of Event</u>	<u>Date Reported</u>	<u>Summary of Event</u>	<u>Vaccine Related</u>
1039	(b) (6)	375	C-T684	905	11/19/90 1/16/91	1/28/91	3/21/91	This 21 year-old female received a first dose of varicella vaccine 11/19/90. At the time of the second vaccination (1/16/91) the subject had flu-like symptoms which worsened during the subsequent 12-day period despite administration of oral antibiotics. On 1/28/91 the subject was admitted to the hospital with a diagnosis of infectious mononucleosis. She was discharged on 1/31/91 on Ciprofloxacin 500 mg b.i.d.	Definitely Not
1023	(b) (6)	375	C-T684	1810	1/25/91 3/26/91	7/24/91	9/6/91	This 38 year-old female received 2 doses of varicella vaccine. During dose 1 follow up she reported no complaints related to vaccination. Four months following the second vaccination during routine gynecologic care, a malignant lesion of the left breast was found. The patient underwent a modified radical mastectomy. Pathology report indicated no lymphatic node involvement.	Definitely Not

XINFWPC.795/92

30APR93

RESULTS (CONT.):

Clinical Complaint Data

Clinical complaint data are available for 9 vaccine recipients and are presented in Table 2.

The vaccine was generally well tolerated.

An injection site reaction was reported by 55.6% (5/9) of the adults. All reactions occurred within two days of vaccination. No vaccinees reported a varicelliform rash at the injection site.

Non-injection site varicella-like rash was reported for 1 vaccinee (11.1%) during the 6-week observation period.

Temperature Data

Temperature data are available for 9 vaccinees and are shown in Table 3.

No vaccinees reported a temperature $\geq 102^{\circ}\text{F}$, oral, during the 42-day follow-up.

Adverse Experiences

One serious adverse experience has been reported in this study. A 30 year-old male (case (b) (6)) who had a history of epilepsy and slight mental retardation, received 2750 PFU of varicella vaccine SC on 5/30/85. On 6/2/85, the patient woke from his sleep with visual disturbances and numbness of the fingers. The symptoms resolved within 5 minutes and the patient recovered. The investigator felt that this experience was similar to those known to precede seizures. On 6/16/85, the patient began to "feel sick" and 2 days later developed a vesicular rash consisting of 75 lesions. This rash was reported in the 42-day observation period.

No other serious adverse experiences have been reported.

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CR647	54	099201	(b) (6)	01/22/89	MOTHER WAS WITH CHILDREN ON THE 22ND AND THEY GOT CHICKEN-POX ON JANUARY 29TH (I ALREADY HAD THEM AS A CHILD) - CHILD NOT EXPOSED ONLY MOM.
			099201	(b) (6)	03/02/89	DAY 1, FLATUS.
		162	099201	(b) (6)	02/20/89	DAY 26 - SMALL TRACE OF BLOOD ON RECTUM AFTER BOWEL MOVEMENT. NO BLOOD VISIBLE IN STOOL, HOWEVER.
		542	099201	(b) (6)	03/16/89	DAYS 36-40 FEVER BLISTER ON LIP
					03/17/89	
					03/18/89	
					03/19/89	
					03/20/89	
		1625	099201	(b) (6)	03/04/89	

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS TABLE 2 (CONT.)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	101701	(b) (6)	04/18/91	STRESSED OUT & MANIC
			101701	(b) (6)	03/15/91	DAY 15 DOSE 1, LIPOSUCTION
	CT684	905	101701	(b) (6)	03/08/91	DAY 2 DOSE 1, ER VISIT - LACERATION
					03/27/91	
	CT685	1155	101701	(b) (6)	03/05/91	YELLOW MUCOUS.
					03/06/91	
					03/07/91	
					03/08/91	
					03/09/91	
					03/10/91	
					03/11/91	
					03/12/91	
					03/13/91	
					03/14/91	
					03/15/91	
2	CT683	1230	101701	(b) (6)	01/08/91	PLUGGED EARS
					01/09/91	
			101701	(b) (6)	03/29/91	
					03/30/91	DAY 2-4 DOSE 2, PAIN FOLLOWING HEMORRHOIDECTOMY
					03/31/91	
	CT684	905	101701	(b) (6)	04/30/91	DAY 25 DOSE 2, URINE BHCG (+) PER CALL FROM PARTICIPANT (PREGNANT)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS TABLE 8 (CONT.)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT683	1230	101701	(b) (6)	03/12/91	DAY 6 DOSE 1, HIGH BP 130/90
	CT684	905	101701	(b) (6)	12/05/90	LARYNGITIS
2	CT683	1230	101701	(b) (6)	06/06/91	DAY 29-32 DOSE 2 SPRAINED THUMB
					06/07/91	
					06/08/91	
					06/09/91	

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	101801	(b) (6)	11/20/90	HOT/COLD FLASHES.
	CT684	905	101801	(b) (6)	11/21/90	DAYS 9-13, 21-24 HIGH BLOOD SUGAR
					11/22/90	
					11/23/90	
					11/24/90	
					11/25/90	
					12/03/90	
					12/04/90	
					12/05/90	
					12/06/90	
2	CT683	1230	101801	(b) (6)	12/16/90	SEBACEOUS CYST. LESION, RIGHT FOREARM, RESEMBLING INSECT BITE, SWELLING, RED, TENDER, SCAB FORMING FIRM KNOT.
					12/17/90	
					12/18/90	
					12/19/90	
					12/20/90	

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
2	CT683	1230	102101	(b) (6)	12/07/90	HEMORRHOIDS RECTAL BLEEDING

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT684	905	102201	(b) (6)	03/24/91	DAY 13-28 DOSE 1, DAY 0-32 34-42 DOSE 2, HOARSENESS IN MORNING
					03/25/91	
					03/26/91	
					03/27/91	
					03/28/91	
					03/29/91	
					03/30/91	
					03/31/91	
					04/01/91	
2	CT684	905	102201	(b) (6)	04/08/91	
					04/09/91	
					04/10/91	
					04/11/91	
					04/12/91	
					04/13/91	
					04/14/91	
					04/15/91	
					04/16/91	
					04/17/91	
					04/18/91	
					04/19/91	
					04/20/91	
					04/21/91	
					04/22/91	
					04/23/91	

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

					04/24/91	
					04/25/91	
					04/26/91	
					04/27/91	
					04/28/91	
					04/29/91	
					04/30/91	
					05/01/91	
					05/02/91	
					05/03/91	
					05/04/91	
					05/05/91	
					05/06/91	
					05/07/91	
					05/08/91	
					05/09/91	
					05/10/91	
					05/12/91	
					05/13/91	
					05/14/91	
					05/15/91	
					05/16/91	
					05/17/91	
					05/18/91	
					05/19/91	
					05/20/91	

TABLE 4 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SEROPOSITIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT684	905	102201	(b) (6)	03/24/91	DAY 13-28 DOSE 1, DAY 0-32 34-42 DOSE 2, HOARSENESS IN MORNING
					03/25/91	
					03/26/91	
					03/27/91	
					03/28/91	
					03/29/91	
					03/30/91	
					03/31/91	
					04/01/91	
2	CT684	905	102201	(b) (6)	04/08/91	
					04/09/91	
					04/10/91	
					04/11/91	
					04/12/91	
					04/13/91	
					04/14/91	
					04/15/91	
					04/16/91	
					04/17/91	
					04/18/91	
					04/19/91	
					04/20/91	
					04/21/91	
					04/22/91	

TABLE 4 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTSINITIAL SEROLOGY: SEROPOSITIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

					04/23/91	
					04/24/91	
					04/25/91	
					04/26/91	
					04/27/91	
					04/28/91	
					04/29/91	
					04/30/91	
					05/01/91	
					05/02/91	
					05/03/91	
					05/04/91	
					05/05/91	
					05/06/91	
					05/07/91	
					05/08/91	
					05/09/91	
					05/10/91	
					05/12/91	
					05/13/91	
					05/14/91	
					05/15/91	
					05/16/91	
					05/17/91	

TABLE 4 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SEROPOSITIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

05/18/91

05/19/91

05/20/91

TABLE 7 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER DOSE DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT684	905	102201	(b) (6)	03/24/91	DAY 13-28 DOSE 1, DAY 0-32 34-42 DOSE 2, HOARSENESS IN MORNING
					03/25/91	
					03/26/91	
					03/27/91	
					03/28/91	
					03/29/91	
					03/30/91	
					03/31/91	
					04/01/91	
2	CT684	905	102201	(b) (6)	04/08/91	
					04/09/91	
					04/10/91	
					04/11/91	
					04/12/91	
					04/13/91	
					04/14/91	
					04/15/91	
					04/16/91	
					04/17/91	
					04/18/91	
					04/19/91	
					04/20/91	
					04/21/91	
					04/22/91	

TABLE 7 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT	DOSE	STUDY	CASE	DATE OF ONSET	DURATION-DESCRIPTION

						04/23/91	
						04/24/91	
						04/25/91	
						04/26/91	
						04/27/91	
						04/28/91	
						04/29/91	
						04/30/91	
						05/01/91	
						05/02/91	
						05/03/91	
						05/04/91	
						05/05/91	
						05/06/91	
						05/07/91	
						05/08/91	
						05/09/91	
						05/10/91	
						05/12/91	
						05/13/91	
						05/14/91	
						05/15/91	
						05/16/91	
						05/17/91	
						05/18/91	

TABLE 7 (CONT.)
LOTUS 1-1 SYSTEMS[illegible]

05/20/91

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	102401	(b) (6)	11/19/90	NIGHT SWEATS

TABLE 9 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT685	1155	102701	(b) (6)	02/08/91	DAYS 24-27, TOOTHBRUSH RELATED CUT.
					02/09/91	
					02/10/91	
					02/11/91	
2	CT685	1155	102701	(b) (6)	04/23/91	

TABLE 11 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SERONEGATIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
2	CT685	1155	102701	(b) (6)	04/23/91	

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	103001	(b) (6)	11/06/90	HURT HAND PLAYING FOOTBALL
			103001	(b) (6)	06/11/91	DAY 26 URINARY DISCOMFORT, SPASH/PAIN
					06/12/91	

TABLE 4 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SERONEGATIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	103001	(b) (6)	11/06/90	HURT HAND PLAYING FOOTBALL

TABLE 7 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	: CT683					
DOSE	: 1230					
DOSE	LOT		DATE OF	DURATION-		
NUM	NUM	DOSE	STUDY	CASE	ONSET	DESCRIPTION

1	CT683	1230	103001	(b) (6)	11/06/90	HURT HAND PLAYING FOOTBALL
			103001	(b) (6)	06/11/91	DAY 26 URINARY DISCOMFORT, SPASH/PAIN
					06/12/91	

TABLE 2 (CONT.)
 LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	103501	(b) (6)	01/09/91	
					01/10/91	ACNE.
					01/11/91	
					01/12/91	
					01/13/91	
					01/14/91	
					01/15/91	
					01/16/91	
					01/17/91	
					01/18/91	DAY 13, SPUTUM?
	CT684	905	103501	(b) (6)	10/18/90	RAPID HEART BEAT & WEAKNESS HYPERTHYROIDISM
	CT685	1155	103501	(b) (6)	12/25/90	COLD EXTREMITIES: HANDS, FEET, DIGITS.
2	CT683	1230	103501	(b) (6)	02/13/91	BLOODY NOSE
					02/14/91	
					02/15/91	

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT684	905	103801	(b) (6)	05/16/91	FREQUENT URINATION.
					05/17/91	

TABLE 4 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SEROPOSITIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT684	905	103801	(b) (6)	05/16/91	FREQUENT URINATION.
					05/17/91	

TABLE 7 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT	DOSE	STUDY	CASE	DATE OF ONSET	DURATION-DESCRIPTION
NUM	NUM	NUM	NUM	NUM	NUM	DATE	DESCRIPTION
1	CT684	905	103801	(b) (6)	05/16/91	FREQUENT URINATION.	
					05/17/91		

TABLE 8 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT683	1230	103801	(b) (6)	12/18/91	
	CT684	905	103801	(b) (6)	12/02/91	DAY 17, DOSE 1, SORE BODY, WEAKNESS IN LIMBS & BACK, NECK VERY SORE, STIFF & TENDER. COLD HANDS & FEET.
					12/03/91	
					12/04/91	
					12/05/91	
					12/06/91	
					12/07/91	DAYS 22-28, DOSE 1, LOST VOICE
					12/08/91	
					12/09/91	
					12/10/91	DAYS 25, 32, 33, DOSE 1, WEAKNESS
					12/11/91	
					12/12/91	
					12/13/91	
					12/16/91	DAYS 31-42, DOSE 1, STILL HAVE FLEM AND THROATCLEARING
					12/18/91	DAY 33, DOSE 1, HURTS TO COUGH, FELT COLD ALL DAY
					12/19/91	
					12/20/91	
					12/21/91	
					12/22/91	
					12/23/91	
					12/24/91	
					12/25/91	
					12/26/91	
					12/27/91	
			103801	(b) (6)	12/27/91	

TABLE 8 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

12/29/91

TABLE 10 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SERONEGATIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT683	1230	103801	(b) (6)	12/18/91	
	CT684	905	103801	(b) (6)	12/27/91	
					12/29/91	

TABLE 13 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT	DOSE	STUDY	CASE	DATE OF ONSET	DURATION-DESCRIPTION
NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM
1	CT683	1230	103801	(b) (6)	12/18/91		

TABLE 13 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER DOSE DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CT684	905	103801	(b) (6)	12/02/91	DAY 17, DOSE 1, SORE BODY, WEAKNESS IN LIMBS & BACK, NECK VERY SORE, STIFF & TENDER. COLD HANDS & FEET.
					12/03/91	
					12/04/91	
					12/05/91	
					12/06/91	
					12/07/91	DAYS 22-28, DOSE 1, LOST VOICE
					12/08/91	
					12/09/91	
					12/10/91	DAYS 25, 32, 33, DOSE 1, WEAKNESS
					12/11/91	
					12/12/91	
					12/13/91	
					12/16/91	DAYS 31-42, DOSE 1, STILL HAVE FLEM AND THROATCLEARING
					12/18/91	DAY 33, DOSE 1, HURTS TO COUGH, FELT COLD ALL DAY
					12/19/91	
					12/20/91	
					12/21/91	
					12/22/91	
					12/23/91	
					12/24/91	
					12/25/91	
					12/26/91	
					12/27/91	
			103801	(b) (6)	12/27/91	

TABLE 13 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

12/29/91

4-14706

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT684	905	104101	(b) (6)	03/14/91	PUSTULE TOP OF LEFT FOOT BETWEEN 3RD & 4TH TOE- VERY SORE (SEVERE ATHLETE'S FOOT)

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT685	1155	104201	(b) (6)	12/15/90	BITTEN BY FAMILY DOG INSIDE LOWER LIP
2	CT685	1155	104201	(b) (6)	03/13/91	DAY 30 FELL AGAINST COUCH-HIT CHIN
					03/18/91	DAY 35 FELL, BLOODY NOSE
					03/23/91	DAY 40 BLOODY NOSE 3 TIMES
			104201	(b) (6)	06/18/91	DAY 29 DOSE 2, STITCHES UNDER NOSE.

TABLE 2 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CT684	905	104501	(b) (6)	05/16/91	DAY 29, INCARCERATED HERNIA SURGERY
					05/17/91	
					05/18/91	
2	CT683	1230	104501	(b) (6)	05/06/91	DOCTOR ON MAY 6 FOR STITCHES

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CH591	3625	107201	(b) (6)	01/29/92	BED WETTING INCREASED DRAMATICALLY DURING 1ST MONTH
			107201	(b) (6)	02/18/92	C/O FEET HURT.
			107201	(b) (6)	02/29/92	RUPTURED EARDRUM.
			107201	(b) (6)	04/25/92	DAY 37 DOSE 1, TUBES IN EARS
	CH592	9000	107201	(b) (6)	01/30/92	EYES RED WITH MUCOUS BUILDUP.
			107201	(b) (6)	02/12/92	DAY 7, LEFT EYE SLIGHTLY PINK.
					02/14/92	DAYS 9-13, DOSE 1, LEFT EYE SLIGHTLY PINK
					02/15/92	
					02/16/92	
					02/17/92	
					02/18/92	
					02/29/92	DAY 24, SOME LABORED-BREATHING & COUGH.
					03/10/92	DAYS 34-39, DOSE 1, RIGHT EYE SLIGHTLY PINK
					03/11/92	
					03/12/92	DAYS 36-39, DOSE 1, LEFT EYE PINK
					03/13/92	
					03/14/92	
					03/15/92	
	CH595	3315	107201	(b) (6)	02/14/92	ALLERGIES - POST NASAL DRIP
2	CH591	3625	107201	(b) (6)	07/02/92	
	CH593	2900	107201	(b) (6)	09/02/92	DAY 40, DOSE 2, MANY DRY HEAVES AND WRETCHING

TABLE 5 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SERONEGATIVE
 ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CH591	3625	107201	(b) (6)	01/29/92	BED WETTING INCREASED DRAMATICALLY DURING 1ST MONTH
			107201	(b) (6)	02/18/92	C/O FEET HURT.
			107201	(b) (6)	02/29/92	RUPTURED EARDRUM.
	CH592	9000	107201	(b) (6)	01/30/92	EYES RED WITH MUCOUS BUILDUP.
			107201	(b) (6)	02/12/92	DAY 7, LEFT EYE SLIGHTLY PINK.
					02/14/92	DAYS 9-13, DOSE 1, LEFT EYE SLIGHTLY PINK
					02/15/92	
					02/16/92	
					02/17/92	
					02/18/92	
					02/29/92	DAY 24, SOME LABORED-BREATHING & COUGH.
					03/10/92	DAYS 34-39, DOSE 1, RIGHT EYE SLIGHTLY PINK
					03/11/92	
					03/12/92	DAYS 36-39, DOSE 1, LEFT EYE PINK
					03/13/92	
					03/14/92	
					03/15/92	
	CH595	3315	107201	(b) (6)	02/14/92	ALLERGIES - POST NASAL DRIP
2	CH591	3625	107201	(b) (6)	07/02/92	
	CH593	2900	107201	(b) (6)	09/02/92	DAY 40, DOSE 2, MANY DRY HEAVES AND WRETCHING

TABLE 5 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: UNKNOWN
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CH591	3625	107201	(b) (6)	04/25/92	DAY 37 DOSE 1, TUBES IN EARS

TABLE 10 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT	DOSE	STUDY	CASE	DATE OF	DURATION-
DOSE	NUM	NUM	DOSE	STUDY	CASE	ONSET	DESCRIPTION

1	CH591	3625	107201	(b) (6)	01/29/92	BED WETTING INCREASED DRAMATICALLY DURING 1ST MONTH	
			107201	(b) (6)	02/18/92	C/O FEET HURT.	
			107201	(b) (6)	02/29/92	RUPTURED EARDRUM.	
			107201	(b) (6)	04/25/92	DAY 37 DOSE 1, TUBES IN EARS	
2	CH591	3625	107201	(b) (6)	07/02/92		

TABLE 10 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT	DOSE	STUDY	CASE	DATE OF ONSET	DURATION-DESCRIPTION
NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM
1	CH592	9000	107201	(b) (6)	01/30/92	EYES RED WITH MUCOUS BUILDUP.	
			107201	(b) (6)	02/12/92	DAY 7, LEFT EYE SLIGHTLY PINK.	
					02/14/92	DAYS 9-13,DOSE 1,LEFT EYE SLIGHTLY PINK	
					02/15/92		
					02/16/92		
					02/17/92		
					02/18/92		
					02/29/92	DAY 24, SOME LABORED-BREATHING & COUGH.	
					03/10/92	DAYS 34-39,DOSE 1,RIGHT EYE SLIGHTLY PINK	
					03/11/92		
					03/12/92	DAYS 36-39, DOSE 1, LEFT EYE PINK	
					03/13/92		
					03/14/92		
					03/15/92		

TABLE 10 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER : CH595		DOSE : 3315				DATE OF	DURATION-
DOSE	LOT					ONSET	DESCRIPTION
NUM	NUM	DOSE	STUDY	CASE			

1	CH595	3315	107201	(b) (6)		02/14/92	ALLERGIES - POST NASAL DRIP

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CH591	3625	107601	(b) (6)	02/28/92	DAY 22 PLUGGED EAR
			107601	(b) (6)	02/29/92	LETHARGY, DAY 18
			107601	(b) (6)	02/18/92	DAY 4, CRAMP
			107601	(b) (6)	03/02/92	DAY 26 BLOODY NOSE
			107601	(b) (6)	02/11/92	DAYS 0,3,5,12,13,15,16,22,24,30 & 37 PASSED OUT
					02/14/92	
					02/16/92	
					02/23/92	
					02/24/92	
					02/26/92	
					02/27/92	
					03/04/92	
					03/06/92	
					03/13/92	
					03/19/92	
			107601	(b) (6)	03/16/92	DAYS 17,18 & 20 NOSE BLEEDS
					03/17/92	
					03/19/92	
	CH592	9000	107601	(b) (6)	03/08/92	HAND, FOOT & MOUTH DISEASE
					03/09/92	
					03/10/92	
			107601	(b) (6)	02/20/92	DAYS 21-23, 28,29 VAGINAL IRRITATION
					02/21/92	
					02/22/92	
					02/27/92	
					02/28/92	

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

			107601	(b) (6)	03/09/92	DAY 20 DOSE 1, HOARSENESS
			107601	(b) (6)	03/23/92	DAY 32 DOSE 1, TUBES PUT IN EARS
			107601	(b) (6)	03/13/92	DAY 42, 3 STITCHES FOR CUT ABOVE RIGHT EYE
			107601	(b) (6)	03/08/92	DAY 31 EMERGENCY ROOM VISIT. FELL AND CUT TOP OF HEAD.
			107601	(b) (6)	03/31/92	VAG INFECTION-STREP.
					04/01/92	
					04/02/92	
					04/03/92	
			107601	(b) (6)	02/29/92	DAY 29 LOSS OF VOICE
			107601	(b) (6)	02/21/92	DAY 8 SNEEZING
			107601	(b) (6)	03/04/92	2 PIMPLE LOOKING BUMPS LEFT-SIDE FACE- VERY SMALL DAY 5, DOSE 1
					03/05/92	
					03/06/92	
CH593	2900		107601	(b) (6)	04/27/92	DAY 31 DOSE 1, BLOODY NOSE
			107601	(b) (6)	04/16/92	DAY 23 DOSE 1, BLOODY NOSE
			107601	(b) (6)	04/28/92	DAY 34 DOSE 1, DIFFICULTY IN HEARING
CH595	3315		107601	(b) (6)	03/29/92	DAY 24 DOSE 1, VIRAL LESIONS BUCCAL MUCOSA MOUTH AND PALATE
			107601	(b) (6)	03/18/92	DAY 23 & 25 BLOODYNOSE
					03/20/92	
			107601	(b) (6)	02/28/92	DAYS 0 & 1 SNEEZING
					02/29/92	
CX342	4120		107601	(b) (6)	03/16/92	DAY 6-7 DOSE 1, EXCESSIVE GAS
					03/17/92	
			107601	(b) (6)	04/16/92	DAY 28, DOSE 1, HOARSENESS

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

			107601	(b) (6)	04/14/92	SEIZURE LIKE ACTIVITY, CT DONE, NO EVIDENCE OF SEIZURE PREVIOUS FEBRILE SEIZURE HISTORY
			107601	(b) (6)	04/12/92	DAY 30, 32, 36, 38, 40 DOSE 1, TINNITUS
					04/14/92	
					04/18/92	
					04/20/92	
					04/22/92	
			107601	(b) (6)	03/28/92	DAY 8-12 DOSE 1, CROUP
					03/29/92	
					03/30/92	
					03/31/92	
					04/01/92	
			107601	(b) (6)	04/08/92	DAY 15-20 DOSE 1, 2ND DEGREE BURN, PALM LT HAND
					04/09/92	
					04/10/92	
					04/11/92	
					04/12/92	
					04/13/92	
			107601	(b) (6)	04/05/92	DAY 11 DOSE 1, SPLINTER
			107601	(b) (6)	04/21/92	DAY 33 DOSE 1, SPRAINED ANKLE
2	CW591	3625	107601	(b) (6)	06/03/92	DAY 8, DOSE 2, MOTHER STATES DIZZINESS, DUE TO HOLDING BREATH WHILE TEMP. BEING TAKEN
	CW592	9000	107601	(b) (6)	06/22/92	DAY 40, DOSE 2, WATERY EYES
			107601	(b) (6)	06/09/92	
	CW595	3315	107601	(b) (6)	07/14/92	DAY 37 DOSE 2, GOT SUNBURNED ON BACK (MILD)

TABLE 10 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER DOSE DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CW592	9000	107601	(b) (6)	03/08/92	HAND, FOOT & MOUTH DISEASE
					03/09/92	
					03/10/92	
			107601	(b) (6)	02/20/92	DAYS 21-23, 28,29 VAGINAL IRRITATION
					02/21/92	
					02/22/92	
					02/27/92	
					02/28/92	
			107601	(b) (6)	03/09/92	DAY 20 DOSE 1, HOARSENESS
			107601	(b) (6)	03/23/92	DAY 32 DOSE 1, TUBES PUT IN EARS
			107601	(b) (6)	03/13/92	DAY 42, 3 STITCHES FOR CUT ABOVE RIGHT EYE
			107601	(b) (6)	03/08/92	DAY 31 EMERGENCY ROOM VISIT. FELL AND CUT TOP OF HEAD.
			107601	(b) (6)	03/31/92	VAG INFECTION-STREP.
					04/01/92	
					04/02/92	
					04/03/92	
			107601	(b) (6)	02/29/92	DAY 29 LOSS OF VOICE
			107601	(b) (6)	02/21/92	DAY 8 SNEEZING
			107601	(b) (6)	03/04/92	2 PIMPLE LOOKING BUMPS LEFT-SIDE FACE- VERY SMALL DAY 5, DOSE 1
					03/05/92	
					03/06/92	
2	CW592	9000	107601	(b) (6)	06/22/92	DAY 40, DOSE 2, WATERY EYES
			107601	(b) (6)	06/09/92	

TABLE 10 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CX342	4120	107601	(b) (6)	03/16/92	DAY 6-7 DOSE 1, EXCESSIVE GAS
					03/17/92	
			107601	(b) (6)	04/16/92	DAY 28, DOSE 1, HOARSENESS
			107601	(b) (6)	04/14/92	SEIZURE LIKE ACTIVITY, CT DONE, NO EVIDENCE OF SEIZURE PREVIOUS FEBRILE SEIZURE HISTORY
			107601	(b) (6)	04/12/92	DAY 30, 32, 36, 38, 40 DOSE 1, TINNITUS
					04/14/92	
					04/18/92	
					04/20/92	
					04/22/92	
			107601	(b) (6)	03/28/92	DAY 8-12 DOSE 1, CROUP
					03/29/92	
					03/30/92	
					03/31/92	
					04/01/92	
			107601	(b) (6)	04/08/92	DAY 15-20 DOSE 1, 2ND DEGREE BURN, PALM LT HAND
					04/09/92	
					04/10/92	
					04/11/92	
					04/12/92	
					04/13/92	
			107601	(b) (6)	04/05/92	DAY 11 DOSE 1, SPLINTER
			107601	(b) (6)	04/21/92	DAY 33 DOSE 1, SPRAINED ANKLE

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CW591	3625	107801	(b) (6)	01/30/92	URINARY FREQUENCY
			107801	(b) (6)	02/26/92	DAY 26 DOSE 1 TAKEN TO HOSPITAL FOR EAR AND HEAD INJURY (X-RAYS)
	CW592	9000	107801	(b) (6)	02/13/92	DAY 2, 4, 10, HOARSENESS
					02/15/92	
					02/21/92	
	CW595	3315	107801	(b) (6)	01/22/92	DAY 2-3 DOSE 1 BLOODY NOSE
					01/23/92	
			107801	(b) (6)	02/21/92	DAY 22 DOSE 1 FELL AND CUT LIP
			107801	(b) (6)	02/19/92	DAY 19 DOSE 1 EAR TUBES REPLACED
			107801	(b) (6)	03/16/92	DAY 14 DOSE 1, TOOTH EXTRACTION
2	CW595	3315	107801	(b) (6)	06/20/92	DAY 38-41 DOSE 2, RAISED SORE, RT THUMB
					06/21/92	
					06/22/92	
					06/23/92	

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TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CW591	3625	108101	(b) (6)	03/30/92	DAY 30 DOSE 1, ER-LACERATION (FELL DOWN STAIRS)
					04/07/92	DAY 38 DOSE 1, LACERATION INFECTED
	CW592	9000	108101	(b) (6)	03/20/92	CORNEAL ABRAISION
					03/21/92	
	CW593	2900	108101	(b) (6)	06/05/92	DAYS 6-8, DOSE 1, HYPERACTIVE
					06/06/92	
					06/07/92	
			108101	(b) (6)	07/17/92	DAY 41, DOSE 1, CUT HAND FROM EMPTY CAN
			108101	(b) (6)	07/12/92	DAY 1 DOSE 1, BLOODY NOSE
	CW595	3315	108101	(b) (6)	02/25/92	DAY 10 CRANKY, WHINY
			108101	(b) (6)	06/06/92	DAY 21 DOSE 1, ANEMIA
2	CW592	9000	108101	(b) (6)	08/28/92	DAY 27, DOSE 2, SWOLLEN EAR - APPARENTLY FROM BUG BITE

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CM595	3315	108801	(b) (6)	03/07/92	
2	CM591	3625	108801	(b) (6)	06/04/92	DAY 15, DOSE 2, RASH ON BOTTOM, I THINK YEAST
					06/05/92	
					06/06/92	
					06/07/92	
					06/08/92	
					06/09/92	
					06/10/92	
					06/11/92	
					06/12/92	
					06/13/92	
					06/14/92	
					06/15/92	
					06/16/92	
					06/17/92	
					06/18/92	
					06/19/92	

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

					03/03/92	
					03/04/92	
					03/05/92	
					03/06/92	
					03/07/92	
					03/08/92	
					03/09/92	
					03/10/92	
					03/11/92	
					03/12/92	
					03/13/92	
					03/14/92	
					03/15/92	
					03/16/92	
					03/17/92	
					03/18/92	
					03/19/92	
					03/20/92	
					03/21/92	
					03/22/92	
					03/23/92	
2	CH591	3625	108901	(b) (6)	05/27/92	DAY 13, DOSE 2, DEVELOPMENTAL MOTOR DELAY (O.V.)
			108901	(b) (6)	06/30/92	DAY 8, DOSE 1, FLU
	CH592	9000	108901	(b) (6)	06/30/92	DAY 8, DOSE 2, FLU

TABLE 2 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CH591	3625	109301	(b) (6)	04/17/92	DAY 36-42 DOSE 1, RED PATCHES ON ARMS, SUNBURN REACTION
					04/18/92	
					04/19/92	
					04/20/92	
					04/21/92	
					04/22/92	
					04/23/92	
			109301	(b) (6)	02/21/92	BIT GLASS, NO CUTS.
	CH592	9000	109301	(b) (6)	02/29/92	FELL ON ICE HURT NECK TOOK TO ER X-RAY INDICATED NOTHING EAR INFECTION SORE THROAT FOUND, DAY 30
			109301	(b) (6)	03/17/92	DIZZINESS
			109301	(b) (6)	02/27/92	DAY 36, 38 FELL BUMPED HEAD
					02/29/92	
	CH595	3315	109301	(b) (6)	03/24/92	DAY 40 CUT FOREHEAD
			109301	(b) (6)	02/29/92	DAY 2-3 RASPY VOICE
					03/01/92	
			109301	(b) (6)	02/17/92	FREQUENT URINATION
2	CH591	3625	109301	(b) (6)	08/16/92	DAY 41, DOSE 2, CELLULITIS BEHIND EAR.
	CH595	3315	109301	(b) (6)	05/31/92	

TABLE 5 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: SERONEGATIVE
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CH591	3625	109301	(b) (6)	04/17/92	DAY 36-42 DOSE 1, RED PATCHES ON ARMS, SUNBURN REACTION
					04/18/92	
					04/19/92	
					04/20/92	
					04/21/92	
					04/22/92	
					04/23/92	
			109301	(b) (6)	02/21/92	BIT GLASS, NO CUTS.
	CH592	9000	109301	(b) (6)	02/29/92	FELL ON ICE HURT NECK TOOK TO ER X-RAY INDICATED NOTHING EAR INFECTION SORE THROAT FOUND, DAY 30
			109301	(b) (6)	02/27/92	DAY 36, 38 FELL BUMPED HEAD
					02/29/92	
	CH595	3315	109301	(b) (6)	03/24/92	DAY 40 CUT FOREHEAD
			109301	(b) (6)	02/29/92	DAY 2-3 RASPY VOICE
					03/01/92	
			109301	(b) (6)	02/17/92	FREQUENT URINATION
2	CH595	3315	109301	(b) (6)	05/31/92	

TABLE 5 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

INITIAL SEROLOGY: UNKNOWN
ASSAY : GP ELISA(EST. TITER)

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CW592	9000	109301	(b) (6)	03/17/92	DIZZINESS

TABLE 8 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER	DOSE	LOT NUMBER	DOSE	STUDY	CASE	DATE OF ONSET	DURATION-DESCRIPTION
1	CW591	3625	109301	(b) (6)	04/17/92	DAY 36-42 DOSE 1, RED PATCHES ON ARMS, SUNBURN REACTION	
					04/18/92		
					04/19/92		
					04/20/92		
					04/21/92		
					04/22/92		
					04/23/92		
			109301	(b) (6)	02/21/92	BIT GLASS, NO CUTS.	
2	CW591	3625	109301	(b) (6)	08/16/92	DAY 41, DOSE 2, CELLULITIS BEHIND EAR.	

TABLE 8 (CONT.)
LISTING OF CASES WITH OTHER SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION
1	CH592	9000	109301	(b) (6)	02/29/92	FELL ON ICE HURT NECK TOOK TO ER X-RAY INDICATED NOTHING EAR INFECTION SORE THROAT FOUND, DAY 30
			109301	(b) (6)	03/17/92	DIZZINESS
			109301	(b) (6)	02/27/92	DAY 36, 38 FELL BUMPED HEAD
					02/29/92	

TABLE 8 (CONT.)
LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER DOSE DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CW595	3315	109301	(b) (6)	03/24/92	DAY 40 CUT FOREHEAD
			109301	(b) (6)	02/29/92	DAY 2-3 RASPY VOICE
					03/01/92	
			109301	(b) (6)	02/17/92	FREQUENT URINATION
2	CW595	3315	109301	(b) (6)	05/31/92	

TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

LOT NUMBER		DOSE		LOT		DOSE		STUDY		CASE		DATE OF		DURATION-		DESCRIPTION	
NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM	NUM

													09/12/92				
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TABLE 2 (CONT.)

LISTING OF CASES WITH 'OTHER' SYSTEMIC COMPLAINTS

DOSE NUM	LOT NUM	DOSE	STUDY	CASE	DATE OF ONSET	DURATION- DESCRIPTION

1	CM591	3625	111001	(b) (6)	03/24/92	BUMP RIGHT ARM (SITE OF ALLERGY SHOT)
	CM595	3315	111001	(b) (6)	03/06/92	DAY 11, 21 AND 36 DOSE 1, ROOT CANAL-DENTIST
					03/16/92	
					03/30/92	

TABLE 3
SEROCONVERSION RATES AND GEOMETRIC MEAN TITERS
ALL CHILDREN AND ADOLESCENTS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
PLA COMBINED STUDIES 0696 AND 0698

STUDY : COMBINE
DOSE NUMBER : 1
ASSAY : FAHA

AGE	NO. VACC.	NO. TESTED	INITIALLY SERONEGATIVE				INITIALLY SEROPOSITIVE					PRE-VACC GEOMETRIC MEAN TITER	POST-VACC GEOMETRIC MEAN TITER
			PRE-VACC SAMPLE ONLY	NO. PAIRS TESTED	CONVERSION RATE (%)	GEOMETRIC MEAN TITER	PRE-VACC SAMPLE ONLY	NO. PAIRS TESTED	NO. WITH 2-FOLD RISE (%)	NO. WITH 4-FOLD RISE (%)			
0-11 MOS	1	1		0				1	0/1 (0.0%)	1/1 (100%)	32.000	256.000	
12-15 MOS	3	3		2	2/2 (100%)	64.000		1	0/1 (0.0%)	1/1 (100%)	2.000	64.000	
16-23 MOS	8	8		8	8/8 (100%)	53.817		0					
2- 4 YRS	43	42		37	37/37 (100%)	41.596		5	0/5 (0.0%)	5/5 (100%)	5.278	73.517	
5-12 YRS	44	43		38	38/38 (100%)	35.056		5	1/5 (20.0%)	4/5 (80.0%)	9.190	73.517	
13-17 YRS	0	0		0				0					
UNKNOWN	0	0		0				0					
TOTAL	99	97		85	85/85 (100%)	39.881		12	1/12 (8.3%)	11/12 (91.7%)	7.127	80.635	

RESERVED 27 TO 84 DAYS POST-VACCINATION.

* BASED ON SAMPLES OBTAINED 27 TO 84 DAYS POST-VACCINATION.

D

TABLE 10 (CONT.)

POST-VACCINATION REACTIONS IN CHILDREN WITH ACUTE LYMPHOCYTIC
LEUKEMIA REPORTED TO CBER/MERCK - RESEARCH LOTS

Study #	Case #	BB-IND	Lot of Vaccine	PFU/Dose	Date Vaccine Administered	Date of Event	Date Reported	Summary of Event	Vaccine* Related
702II	(b) (6)	1462	C-H198	4358	4/20/87	5/24/87	6/87	This 4 year-old female was diagnosed with high risk acute lymphocytic leukemia on 11/22/85 and was in remission on 12/23/85. Approximately 16 months later, she was vaccinated. Thirty-four days post-vaccination, she developed a vesicular rash which lasted for 17 days. The maximum number of lesions was 300. The child was started on oral acyclovir 10 days post-vaccination when there were about 100 lesions. The child was hospitalized the next day and started on IV acyclovir. The next day the child had a temperature of 104°F, oral. The following day she complained of abdominal pain for the next three days. She began to improve on the 15th day after the rash started. Vaccine-type virus was isolated from one of the child's lesions. She recovered without any residual problems.	Yes
702II	(b) (6)	1462	C-H198	4358	5/8/87	6/7/87	Reported as part of annual report for NIAID IND	This 8 year-old child was diagnosed with low-risk acute lymphocytic leukemia on 7/11/85 and was in remission on 8/11/85. Approximately 21 months later he was vaccinated. Ten days post-vaccination, he was exposed to varicella and administered VZIG. Twenty days later he developed varicella. The rash consisted of 20 lesions and the child had a fever. He was administered IV acyclovir. No attempt was made at culturing any of the child's lesions. The child recovered without any residual problems.	Probably Not

*Clinical investigator's assessment.

TABLE 22 (CONT.)

POST-VACCINATION REACTIONS IN CHILDREN WITH ACUTE LYMPHOCYTIC
LEUKEMIA REPORTED TO CBER/MERCK - CONSISTENCY LOTS

Study #	Case #	BB-IND	Lot of Vaccine	PFU/Dose	Date Vaccine Administered	Date of Event	Date Reported	Summary of Event	Vaccine* Related
702II	(b) (6)	1462	C-L303	3450	10/23/85	11/13/85	11/25/85	This 6-1/2 year old male with acute lymphocytic leukemia (low risk) was vaccinated 19-1/2 months in remission. Chemotherapy was suspended for one week prior to and one week after vaccination. Approximately 20 days post-vaccination he developed a rash which evolved into 500 vesicles. He was hospitalized and started on intravenous acyclovir. The rash lasted 13 days.	Probable
702II	(b) (6)	1462	C-L805	3500	11/27/85	12/12/85	12/30/85	This 6 year-old female was diagnosed with acute lymphocytic leukemia (low risk) on 8/8/84 and was in remission on 9/12/84. Fifteen days post-vaccination she developed a vesicular rash which lasted for 25 days and consisted of 1000 lesions. The child developed severe abdominal pain and mild interstitial pneumonia and was treated with IV acyclovir. The child recovered though cosmetic surgery was required due to persistence necrotic lesions on the face.	Probable
702II	(b) (6)	1462	C-L805	3500	12/3/85	12/23/85	1/14/86	This 12 year-old female was diagnosed with acute lymphocytic leukemia (low risk) on 1/1/83. She was in remission by 2/1/83. Approximately 2 years later she was vaccinated. Twenty days post-vaccination she developed a rash which lasted for 17 days and consisted of 1000 lesions. She complained of severe abdominal pain and backache. The child was hospitalized and placed on IV acyclovir. Vaccine-type virus was isolated from one of the child's lesions. She recovered without residual problems.	Yes

*Clinical investigator's assessment.

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TABLE 22 (CONT.)

POST-VACCINATION REACTIONS IN CHILDREN WITH ACUTE LYMPHOCYTIC
LEUKEMIA REPORTED TO CBER/MERCK - CONSISTENCY LOTS

<u>Study #</u>	<u>Case #</u>	<u>BB-IND</u>	<u>Lot of Vaccine</u>	<u>PFU/Dose</u>	<u>Date Vaccine Administered</u>	<u>Date of Event</u>	<u>Date Reported</u>	<u>Summary of Event</u>	<u>Vaccine* Related</u>
702II	(b) (6)	1462	C-L308	2750	12/4/85	12/29/85	12/30/85	This 5 year-old male was diagnosed with acute lymphocytic leukemia on 7/3/84 and was in remission on 8/7/84. He was vaccinated approximately 16 months later. Twenty-five days post-vaccination, this child developed a rash which lasted 6 days and consisted of 1000 lesions. The child had a temperature of 104°F, oral, for one day and back and side pain. He was hospitalized and placed on IV acyclovir. He recovered without any residual problems.	Probable

*Clinical investigator's assessment.

XPROJECT.2060/06APR93

4-17880

TABLE 22 (CONT.)

VARICELLA VACCINE COLLABORATIVE STUDY
DEATHS AMONG RECIPIENTS OF CONSISTENCY LOTS

- (b) (6) Onset of ALL† June 1981; varicella vaccine February 11, 1985 and May 20, 1985; chemotherapy suspended for first dose only. Relapses (marrow and CNS) diagnosed 7/13/81, 5/20/85 and 8/15/85. Died at home of progressive leukemia (b) (6). *
- (b) (6) Onset of ALL† December 1981; varicella vaccine February 11, 1985 and May 20, 1985; chemotherapy suspended for first dose only. Relapses October 1983 and January 1986. Died in relapse of fungal infection (b) (6). *
- (b) (6) Onset of ALL† 1984; varicella vaccine February 22, 1985 and May 21, 1985; chemotherapy suspended for first dose only; relapse November 1985 and April 1986; expired (b) (6) of leukemia. *
- (b) (6) Onset of ALL† 1984; varicella vaccine 3/28/85 and 7/8/85 (chemotherapy suspended for first dose only); died (b) (6) due to complications of ALL†.**
- (b) (6) Onset of ALL† January 1984; varicella vaccine 3/29/85 and 7/3/85; relapsed 7/85 and subsequently had an allogenic bone marrow transplant; died (b) (6) due to a pulmonary hemorrhage.**
- (b) (6) Onset of ALL† 1984; varicella vaccine May 28, 1985 and August 26, 1985; chemotherapy suspended for first dose only; relapses 4/10/84, 3/1/86, 9/2/86, 3/1/87. Expired (b) (6) of leukemia. *
- (b) (6) Onset of ALL† 1984; varicella vaccine 8/1/85 and 10/31/85 (chemotherapy suspended for first dose only); died (b) (6) (b) (6) due to complications of ALL†. *

† ALL = Acute lymphocytic leukemia

* Death reported under the NIAID IND.

** Death reported under Merck IND.

TABLE 22 (CONT.)

VARICELLA VACCINE COLLABORATIVE STUDY
DEATHS AMONG RECIPIENTS OF CONSISTENCY LOTS

- (b) (6) Onset of ALL† February 1984; varicella vaccine August 1985; chemotherapy suspended 2 weeks; bone marrow relapse July 1986; relapse October 1986; expired (b) (6) from complications of ALL†. *
- (b) (6) Onset of ALL† 1984; varicella vaccine 10/14/85; chemotherapy suspended; relapse 11/85; bone marrow transplant 1/86; relapse #2 4/8/86; expired (b) (6) of leukemia. *
- (b) (6) Onset of ALL† 1984; varicella vaccine 11/4/85; (chemotherapy suspended); died (b) (6) due to complications of ALL†. **
- (b) (6) Onset of ALL† 1984; varicella vaccine 11/15/85; (chemotherapy suspended); relapse 11/85; died (b) (6) due to recurrent ALL† unresponsive to chemotherapy. *
- (b) (6) Onset of ALL† 1984; varicella vaccine 11/27/85; (chemotherapy suspended); bone marrow and testicular relapse 8/87, second bone marrow relapse 1/89; died (b) (6) due to complications of ALL†. **

† ALL = Acute lymphocytic leukemia

* Death reported under the NIAID IND.

** Death reported under Merck IND.



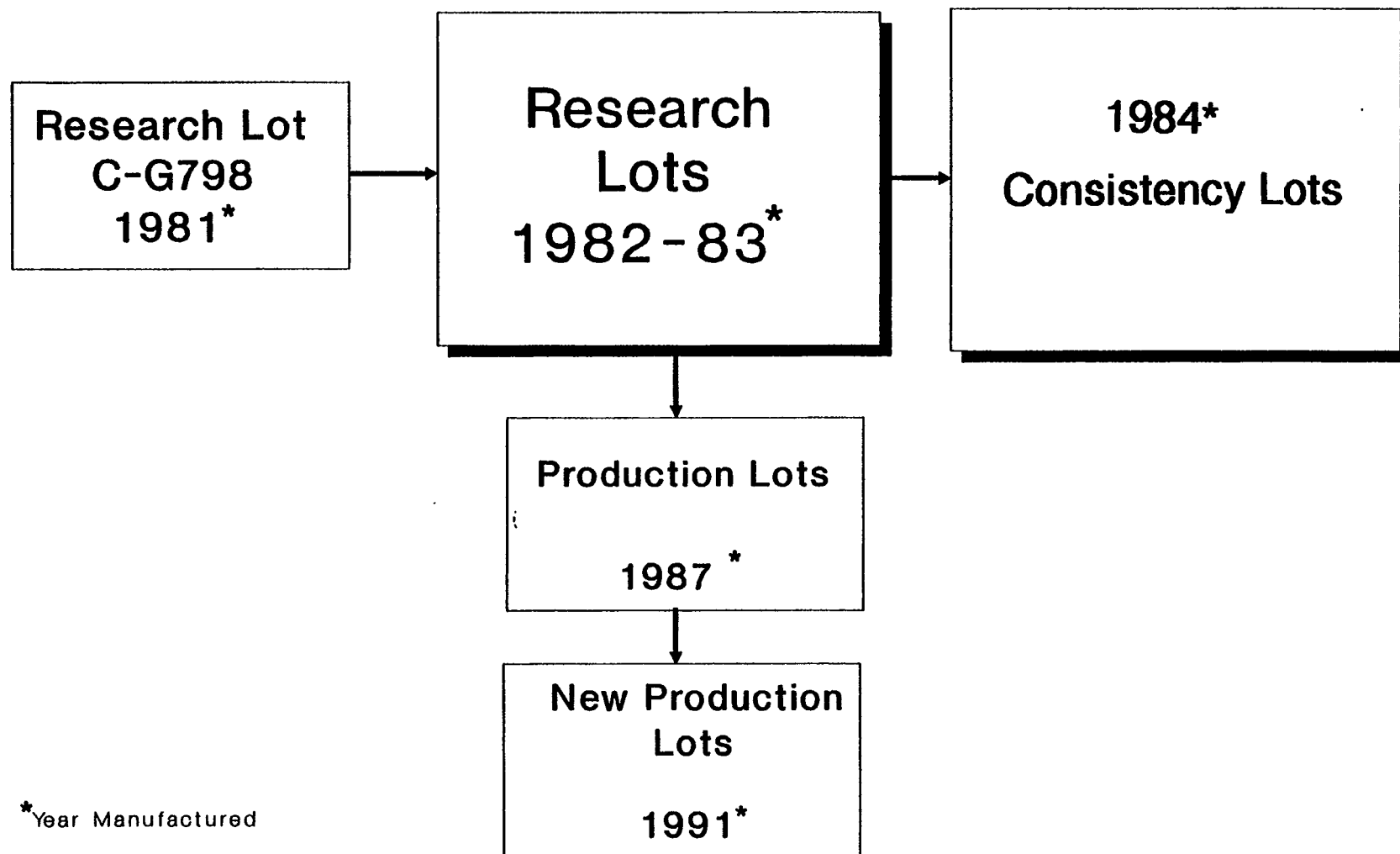
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VARIVAX®

Clinical Trials

Live Varicella Vaccine (Oka/Merck)



Clinical Data

X. Appendices

X. Appendices

H. Clinical Trials in Children with Solid Tumors and Nephrotic Syndrome

1. Children with Solid Tumors

a. Study Design

One clinical trial with the live varicella vaccine (Oka/Merck) was conducted in children with underlying solid tumors (primarily rhabdomyosarcoma and Wilm's tumor) from 1985 - 1987. All participants met the following eligibility criteria:

1. Serologically susceptible to varicella.
2. No known exposure to varicella in the 3 weeks prior to vaccination.
3. No receipt of VZIG, immune globulin or viral products in the 4 months prior to vaccination.
4. No radiation therapy for the 2 months prior to vaccination.
5. A total lymphocyte count of at least 700 cells/mm³.
6. A platelet count greater than 100,000/mm³.

1. Children with Solid Tumors (Cont.)

7. A serum IgG level greater than 100 mgm%.

8. A positive response of lymphocytes in vitro to at least one mitogen.

9. No sensitivity to neomycin.

The study was conducted with the research and consistency lots of vaccine. The research lots were lots of vaccine made on a small-scale in the research facilities from 1981-82. The consistency lots were made in 1984 in the standard manufacturing facilities for vaccines.

Each child was scheduled to receive two injections of vaccine, generally administered 3 months apart, and was followed clinically for 56 days after each injection. The parent/guardian of each child was asked to complete a vaccination report card documenting daily clinical complaints and temperatures.

Clinical Data

X. Appendices

b. Results1. Research Lotsa) Enrollment

Nine children with solid tumors, ages 3 to 8 years, were vaccinated with research Lot C-H198. Two additional children who received one of the consistency lots for their first injection of vaccine received Lot C-H198 for their second injection.

b) Safety

Two serious adverse reactions were reported among recipients of Lot C-H198. One child with rhabdomyosarcoma and one child with Wilm's tumor died due to their underlying illness; neither death was considered to vaccine related.

The vaccine was generally well tolerated. Clinical complaints reported by parents without regard to causality for the 56 days post-vaccination for the children vaccinated with Lot C-H198 are shown in Table 1 for dose 1 and Table 2 for dose 2. Maximum temperatures reported during the 56-day observation period by injection number are shown in Tables 3 and 4, respectively.

b) Safety (Cont.)

After the first injection of vaccine, one child (11%) had a rash at the injection site, 3 (33%) had a reaction at the injection site, and 2 (22%) reported a varicella-like rash after the first injection. Twenty-seven percent (3/11) of the children reported a local reaction at the injection site after the second injection; one child had a varicella-like rash after the second injection.

A temperature $\geq 102^{\circ}\text{F}$, oral, was reported by 22% (2/9) of the children after the first injection of vaccine; no child had a temperature $\geq 102^{\circ}\text{F}$, oral, after the second injection.

c) Serologic Results/Persistence

The overall seroconversion rate (FAMA) was 33% (3/9) after one injection of vaccine and 89% (8/9) after two injections of vaccine.

c) Serologic Results/Persistence (Cont.)

Persistence of antibody was measured by FAMA at 1, 2, 3 and 4 years after the initial injection. Antibody was detected in 33% (2/6) at 1 year, 40% (2/5) at 2 years, 25% (1/4) at 3 years and 50% (2/4) at 4 years.

d) Efficacy

No formal studies of the efficacy of the vaccine in children with solid tumors were conducted.

e) Revaccinations

No child was revaccinated with Lot C-H198 due to loss of antibody or lack of seroconversion after the first two injections.

f) Varicella Cases

No cases of varicella have been reported among recipients of Lot C-H198.

g) Zoster

No cases of zoster have been reported among children with solid tumors who received Lot C-H198.

2. Consistency Lots

a) Enrollment

Eleven children with solid tumors, ages 1 to 5 years, were vaccinated with one of four consistency lots (C-L303, C-L306, C-L308 or C-L805).

b) Safety

The consistency lots of vaccine were generally well tolerated. No serious adverse reactions were reported. Clinical complaints without regard to causality by injection number for the children vaccinated with the consistency lots are shown in Tables 5 and 6, respectively. Maximum temperatures reported during the 56-day observation period by injection number are shown in Tables 7 and 8, respectively.

Clinical Data

X. Appendices

b) Safety (Cont.)

No injection site rashes or reactions were reported after the first or second injection of vaccine. Thirty-six percent (4/11) of the children reported a varicella-like rash after the first injection; 14% (1/7) reported a rash after the second injection.

A temperature $\geq 102^{\circ}\text{F}$, oral, was reported by 9% (1/11) and 14% (1/7) of the children after the first and second injection, respectively.

c) Serologic Results/Persistence

The overall seroconversion rate (FAMA) was 82% (9/11) after one injection of vaccine and 83% (5/6) after two injections of vaccine.

Persistence of antibody was measured by FAMA 1 and 2 years after the initial injection. Antibody was detectable in 67% (4/6) at 1 year and 75% (3/4) at 2 years.

d) Efficacy

No formal studies of the efficacy of the vaccine in children with solid tumors were conducted.

e) Revaccinations

No child was revaccinated with the consistency lots due to loss of antibody or lack of seroconversion after the first 2 injections.

f) Varicella Cases

No cases of varicella have been reported among recipients of the consistency lots.

g) Zoster

No cases of zoster have been reported among children with solid tumors who received one of the consistency lots.

2. Children with Nephrotic Syndrome

a. Study Design

One clinical trial was conducted from 1985 - 1986 to evaluate the use of the 5 consistency lots of vaccine in children with nephrotic syndrome. All participants met the following criteria:

1. A negative clinical history of varicella.
2. No known immune deficiency, neoplastic disease, or sensitivity to neomycin.
3. No known exposure to varicella in the 4 weeks prior to vaccination.
4. No other vaccinations (DPT, MMR, OPV, etc.) for a month before and after receipt of this vaccine.
5. No immune globulin, VZIG, blood transfusion or other blood products during the 3 months prior to vaccination.

2. Children with Nephrotic Syndrome (Cont.)

6. Total lymphocyte count $>1000/\text{mm}^3$, normal platelet count, normal (or relatively normal) immunoglobulin levels.

7. Physician-diagnosed steroid-dependent or steroid-responsive nephrotic syndrome in remission (proteinuria-free for at least 2 weeks on alternate-day or no prednisone therapy). The patient's urine was required to be dipstick protein negative or trace on the day of vaccination. (A steroid-dependent child was defined as a patient who attained full remission, i.e., no proteinuria, when steroids were given but who relapsed with proteinuria when the steroid dosage was lowered below a certain "critical" level which appeared to vary between individual patients. A steroid-responsive patient was defined as a patient who was able to remain in remission while steroids were tapered and discontinued.)

Clinical Data

X. Appendices

b. Results1. Enrollment

Six children with nephrotic syndrome and off all steroid therapy received one injection of 1 of 5 consistency lots (C-L303, C-L306, C-L308, C-L803 or C-L805). This study was cancelled after enrollment of the first 6 children because of the increased reactivity of the consistency lots in children with acute lymphocytic leukemia (see Appendix E).

2. Safety

The vaccine was generally well tolerated. No serious adverse reactions were reported among recipients of the consistency lots. One child reported a rash at the injection site; no child had any other reactions at the injection site. One child reported a varicella-like rash.

No child developed a temperature $\geq 102^{\circ}\text{F}$, oral after vaccination.

3. Serologic Results/Persistence

The overall seroconversion rate (ELISA) was 100% (6/6) after one injection of vaccine. The geometric mean titer was 15.4.

No persistence data were obtained in this study.

4. Efficacy

No formal studies of the efficacy of the vaccine in children with nephrotic syndrome were conducted.

5. Revaccinations

No child was revaccinated with the consistency lots due to loss of antibody or lack of seroconversion after the first injection.

6. Varicella Cases

No cases of varicella have been reported among the 6 children with nephrotic syndrome vaccinated with the consistency lots.

7. Zoster

No cases of zoster have been reported among children with nephrotic syndrome who received 1 of the 5 consistency lots.

TABLE 1
 PATIENT COUNT CLINICAL COMPLAINTS
 ALL CHILDREN WITH SOLID TUMORS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
 PLA - ALL LOTS

STUDY : COMBINE
 TREATMENT : VARICELLA
 LOT NUMBER : CH198
 DOSE : 4358 PFU/0.25 ML

CLINICAL COMPLAINTS *****	(9 PATIENTS) - DOSE 1							NUMBER WITH COMPLAINTS *****
	DAYS POST VACCINATION							
	0-2 *****	3-6 *****	7-13 *****	14-20 *****	21-27 *****	28-34 *****	35-56 *****	
LOCAL REACTION (INJ. SITE)	0 (0.0%)	2 (22.2%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	3 (33.3%)
ERYTHEMA	0 (0.0%)	2 (22.2%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	3 (33.3%)
SORENESS	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
SMELLING	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
RASH	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
SYSTEMIC	2 (22.2%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	4 (44.4%)
UPPER RESPIRATORY ILLNESS	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
HEADACHE	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
VARICELLA-LIKE RASH	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
PERSONS WITH COMPLAINTS	2 (22.2%)	2 (22.2%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	5 (55.6%)
PERSONS WITH NO COMPLAINTS	7 (77.8%)	7 (77.8%)	8 (88.9%)	8 (88.9%)	8 (88.9%)	9 (100.0%)	9 (100.0%)	4 (44.4%)
PERSONS WITH NO DATA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 2
PATIENT COUNT CLINICAL COMPLAINTS
ALL CHILDREN WITH SOLID TUMORS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
PLA - ALL LOTS

STUDY : COMBINE
TREATMENT : VARICELLA
LOT NUMBER : CH198
DOSE : 4358 PFU/0.25 ML

CLINICAL COMPLAINTS *****	(11 PATIENTS) - DOSE 2							NUMBER WITH COMPLAINTS *****
	DAYS POST VACCINATION							
	0-2	3-6	7-13	14-20	21-27	28-34	35-56	
LOCAL REACTION (INJ. SITE)	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (27.3%)
ERYTHEMA	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
SORENESS	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SWELLING	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
INDURATION	1 (9.1%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
SYSTEMIC	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	3 (27.3%)
UPPER RESPIRATORY ILLNESS	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
VARICELLA-LIKE RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)
PERSONS WITH COMPLAINTS	2 (18.2%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	3 (27.3%)
PERSONS WITH NO COMPLAINTS	9 (81.8%)	9 (81.8%)	10 (90.9%)	10 (90.9%)	11 (100.0%)	11 (100.0%)	10 (90.9%)	8 (72.7%)
PERSONS WITH NO DATA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 3
PATIENT COUNT MAXIMUM TEMPERATURES
ALL CHILDREN WITH SOLID TUMORS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
PLA - ALL LOTS

STUDY : COMBINE
TREATMENT : VARICELLA
LOT NUMBER : CH198
DOSE : 4358 PFU/0.25 ML

MAX TEMPERATURE (DEG F, ORAL)	(9 PATIENTS) - DOSE 1								NUMBER WITH MAX TEMP
	DAYS POST VACCINATION								
	0-2	3-6	7-13	14-20	21-27	28-34	35-56		
*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
NORMAL	9 (100.0%)	8 (88.9%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	8 (88.9%)	9 (100.0%)		7 (77.8%)
102 - 102.9	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)		2 (22.2%)
TEMPERATURE TAKEN	9	9	9	9	9	9	9		9
TEMPERATURE NOT TAKEN	0	0	0	0	0	0	0		0

TABLE 4
 PATIENT COUNT MAXIMUM TEMPERATURES
 ALL CHILDREN WITH SOLID TUMORS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
 PLA - ALL LOTS

STUDY : COMBINE
 TREATMENT : VARICELLA
 LOT NUMBER : CH198
 DOSE : 4358 PFL/0.25 ML

MAX TEMPERATURE (DEG F, ORAL)	(11 PATIENTS) - DOSE 2								NUMBER WITH MAX TEMP
	DAYS POST VACCINATION								
	0-2	3-6	7-13	14-20	21-27	28-34	35-56		
*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
NORMAL	11 (100.0%)	10 (90.9%)	11 (100.0%)	11 (100.0%)	11 (100.0%)	11 (100.0%)	11 (100.0%)		10 (90.9%)
100 - 100.9	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
TEMPERATURE TAKEN	11	11	11	11	11	11	11		11
TEMPERATURE NOT TAKEN	0	0	0	0	0	0	0		0

TABLE 5
 PATIENT COUNT CLINICAL COMPLAINTS
 ALL CHILDREN WITH SOLID TUMORS WHO RECEIVED OKA/MERCK VARICELLA VACCINE
 PLA - CONS LOTS

STUDY : COMBINE
 TREATMENT : VARICELLA

CLINICAL COMPLAINTS *****	(11 PATIENTS) - DOSE 1							NUMBER WITH COMPLAINTS *****
	DAYS POST VACCINATION							
	0-2 *****	3-6 *****	7-13 *****	14-20 *****	21-27 *****	28-34 *****	35-56 *****	
SYSTEMIC	2 (18.2%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (9.1%)	2 (18.2%)	5 (45.5%)
UPPER RESPIRATORY ILLNESS	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
VARICELLA-LIKE RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (9.1%)	2 (18.2%)	4 (36.4%)
PERSONS WITH COMPLAINTS	2 (18.2%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (9.1%)	2 (18.2%)	5 (45.5%)
PERSONS WITH NO COMPLAINTS	9 (81.8%)	11 (100.0%)	11 (100.0%)	10 (90.9%)	11 (100.0%)	10 (90.9%)	9 (81.8%)	6 (54.5%)
PERSONS WITH NO DATA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 1

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=87 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
077801	(b) (6)	3.1	1361	99	31	31	NS	8.4(+)

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=872 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
077801	(b) (6)	3.6	2173	99	15		LC	13.6(+)
077801		12.2	884	101	12	12	NS	50.5(+)
078101		12.9	546	101	25		LC	

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=950 LOT=CK472 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
081801	(b) (6)	2.3	2521	FEVER	UNK		NS	11.4(+)
081801		10.6	2549	NORM	50		NS	2.8(+)
081801		3.2	1655		300	150	NS	2.5(+)
081801		4.6	93	102	4		NS	18.4(+)
081801		5.7	235	NORM	5	5	NS	
081801		1.3	1238	FEVER	33		LC	
081801		1.3	947	FEVER	5	3	NS	
082601		1.4	2546	FEVER	20	20	NS	1.8(+)
082601		1.3	946	100	70	70	NS	0.3(+)
082601		1.0	2132	100	10		LC	8.7(+)
082601		1.0	1739		30	15	NS	6.9(+)
082601		1.3	941	NORM	6	6	NS	7.7(+)
082601		1.6	660	FEVER	100	100	LC	0.3(-)
082601		1.9	1436	FEVER	12	12	NS	3.4(+)
082601		1.5	1392	FEVER	70	70	LC	
082601		1.2	645	99	7	5	LC	
082601		1.9	1630	100	14	14	NS	2.6(+)
082601		1.4	907	FEVER	10	10	NS	19.8(+)
082601		1.6	973	FEVER	41	41	NS	2.7(+)
082601		1.4	2301	102	25	5	NS	0.3(-)
082601		1.6	1807	NORM	13	13	NS	4.1(+)
082601		1.0	1571	FEVER	40	40	NS	0.7(+)
082601		2.2	723	NORM	7		LC	5.6(+)
082601		1.5	1560	NORM	40	40	NS	6.0(+)
082601		1.9	1658	NORM	30		NS	1.7(+)
082601		4.8	632		20	20	NS	1.0(+)

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TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=950 LOT=CK472 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
082601	(b) (6)	4.2	1647	101	100	100	NS	0.3(-)
082601		3.1	1564	FEVER	100	100	NS	6.2(+)
082701		1.3	940	NORM	50	25	NS	1.0(+)
082701		1.5	864	101	360		LC	9.1(+)
084501		2.2	1267	NORM	70	10	NS	2.1(+)
084501		2.3	2117	NORM	28	3	LC	8.6(+)
084501		1.8	1742	100	50	25	NS	1.3(+)
084501		3.6	1031	FEVER	254	38	NS	
084501		1.3	2098	102	14	3	LC	0.3(+)
084501		2.3	207	NORM	9		NS	0.8(+)
084501		5.8	1626	102	50	40	NS	1.1(+)
084501		7.1	960	NORM	6		NS	
084501		4.2	927	NORM	29	29	NS	2.5(+)
084501		2.7	745	98	6	6	LC	2.8(+)
084501		4.5	861	NORM	29	29	NS	4.7(+)
084501		1.8	489	NORM	68		LC	1.8(+)
084501		4.2	121	100	39	2	NS	
084501		12.3	1984	102	76	16	LN	4.8(+)
084501		2.1	445	NORM	12		NS	16.1(+)
084501		3.8	1305	102	120	50	LC	1.2(+)
084801		5.6	1823	FEVER	5		NS	
084801		1.4	1322	102	210	10	NS	
084801		9.1	543	NORM	20	2	NS	
084801		5.0	1107	NORM	40	5	LC	
084801		4.8	952	100	50	2	LC	
084801		2.8	692	99	38	38	NS	
085001		2.8	986	99	30	30	NS	1.3(+)
085001		2.2	439	99	8	2	LC	
085001		2.8	973	98	9		NS	10.8(+)
085001		4.2	829	NORM	20		NS	1.3(+)
085001		1.3	905	NORM	12	12	NS	12.4(+)
085701		1.3	1554	101	61	13	NS	0.8(+)
085701		1.3	1362	NORM	22		NS	7.4(+)
085701		1.3	2232	NORM	49		NS	0.8(+)
085701		1.3	1551	NORM	30		NS	1.0(+)
085701		1.9	563	NORM	100	2	NS	0.9(+)
085701		1.3	376	NORM	51	1	NS	3.5(+)
085701		1.3	1618	NORM	78	1	NS	3.5(+)
085701		1.5	1616	NORM	6		LC	2.4(+)
085701		1.2	1612	NORM	6		NS	1.4(+)
085701		1.3	1834	100	20	2	NS	17.0(+)
085701		1.4	386	NORM	25		NS	3.6(+)
085701		1.4	1612	101	30		NS	3.6(+)
085701		1.3	1519	101	61	13	NS	>25.0(+)
085701		1.5	1473	NORM	UNK		NS	3.3(+)

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TABLE 1 (CONT.)
LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RES PROTOCOL-001 DOSE(PFU)=950 LOT=CK472 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
085701	(b) (6)	1.3	1593	NORM	10		NS	2.2(+)
085701		1.3	2024	103	516	117	NS	2.4(+)
085701		1.3	372	NORM	25		LC	11.4(+)
085701		1.3	1935	NORM	70	2	NS	11.4(+)
085701		1.2	1921	102	417	1	LC	1.3(+)
085701		1.2	1593	101	3		NS	1.3(+)
085701		1.3	1929	NORM	70	2	LC	7.5(+)
755201		3.3	1677		20		NS	
755201		3.4	1389	NORM	60	20	LC	
755201		5.6	773	NORM	93	3	NS	
755201		4.4	1351	100	23	11	LN	
755201		9.1	1258	100	80	10	NS	
755201		6.3	919	102	12	12	LC	
755201		6.8	583	99	157	157	LC	1.2(+)
755201		4.8	1338	NORM	38	15	NS	
755201		2.2	1001		24	24	NS	
755201		5.8	2503	NORM	57	36	NS	
755201		2.7	1281	102	40		NS	2.5(+)
755201		10.3	1658	101	100	50	NS	1.4(+)

----- LOTS=RES PROTOCOL-001 DOSE(PFU)=1743 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
077801	(b) (6)	6.0	2400	NORM	2		LC	
077801		1.4	2853	NORM	45	3	LC	12.5(+)
077801		6.4	1345		20		NS	2.8(+)
077801		7.2	1618	99	36		NS	10.5(+)

TABLE 1 (CONT.)
 LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
 HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=8715 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
077801	(b) (6)	2.9	2400	100	60	20	LC	
077801		2.8	2853	NORM	54	6	LC	20.7(+)
077801		8.4	2567	103	53		LC	13.6(+)
077801		3.8	2044	100	70	10	LC	112.2(+)
077801		1.8	716	NORM	37	2	LC	13.2(+)
077801		9.9	1371	NORM	30		LC	6.1(+)
077801		8.3	1391	NORM	7	7	NS	9.2(+)
077801		2.8	1061	99	11	11	LC	10.8(+)
077801		4.8	1193	NORM	27		NS	7.5(+)
755201		3.2	712	FEVER	79		LC	

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RES PROTOCOL=001 DOSE(PFU)=17430 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
074501	(b) (6)	5.1	3069	FEVER	15		NS	
074501		2.4	2137	99	20	2	NS	
074501		2.8	1477		16	1	LC	
074501		1.5	1412	NORM	30	2	LC	
075501		5.3	1375	NORM	62	58	LC	23.1(+)
075501		1.9	1297	NORM	84	84	NS	
075501		2.8	1516		9		NS	
075501		4.8	1514	NORM	18		NS	6.4(+)
075501		4.8	1700	NORM	12		NS	16.9(+)
075501		1.0	1621	99	28		LN	29.1(+)
075501		2.4	1497	98	98		LC	
075501		3.1	1511	FEVER	6		LS	18.5(+)
075501		1.4	1568	99	15		NS	
075501		8.8	892	100	286		LC	
075501		2.8	1961	NORM	50	30	LC	16.5(+)
075501		2.8	2683	FEVER	11	1	LC	21.0(+)
075501		2.1	2342	NORM	25	10	LC	36.0(+)
075501		6.5	1998	NORM	100		LC	14.4(+)
075501		3.0	236	100	17	1	LC	12.4(+)
075501		7.8	1084	103	58		LS	
075501		3.8	1248	FEVER	33	33	NS	
075501		2.9	2652	FEVER	58	10	LS	14.5(+)
075501		10.6	1928	NORM	20	10	NS	8.3(+)
075501		7.5	2279	NORM	30	3	LC	
075501		1.3	2262	102	17	3	LC	
075501		4.3	1125	NORM	15		LC	
075501		4.5	1115		27		LC	
075501		4.5	2280	NORM	16		NS	
075501		8.3	1563	NORM	12	9	NS	14.1(+)
075501		9.8	1563		209	140	LC	16.8(+)
075501		5.2	759	102	60	30	LC	24.4(+)
755201		5.3	1524		50	10	NS	
755201		4.4	997	99	97	97	LC	

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1000 LOT=CR319 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
095301	(b) (6)	8.5	177	NORM	18	5	LC	4.4(+)
095301	(b) (6)	1.9	944	NORM	100		LC	11.9(+)
095301	(b) (6)	2.5	1613	101	20	5	NS	7.8(+)
095301	(b) (6)	1.0	1451	97	42	14	LC	16.9(+)
095301	(b) (6)	2.7	1664	100	74	20	LC	7.9(+)
095301	(b) (6)	1.8	1526	NORM	31	3	LC	2.4(+)
095301	(b) (6)	1.8	1285	NORM	12		LN	2.4(+)
095301	(b) (6)	8.1	1234	FEVER	55		NS	8.6(+)
095301	(b) (6)	1.8	1247	99	331	100	LC	4.6(+)
095301	(b) (6)	5.2	858	NORM	20	11	NS	1.3(+)
095301	(b) (6)	2.1	1882	99	278	231	NS	1.5(+)
095301	(b) (6)	1.3	1855	99	65	40	NS	3.6(+)
095301	(b) (6)	1.3	1875	NORM	10	10	NS	16.5(+)
095301	(b) (6)	5.0	490	101	6	1	LC	7.0(+)
095301	(b) (6)	1.8	485	NORM	20		NS	8.8(+)
095301	(b) (6)	4.4	294	99	7	6	LC	5.4(+)
095301	(b) (6)	1.4	1779	NORM	100	20	NS	4.3(+)
095301	(b) (6)	3.3	598	NORM	25	15	LC	15.3(+)
095301	(b) (6)	1.2	1306	102	51	10	NS	
095301	(b) (6)	1.3	1292	98	47	11	LC	14.2(+)
095301	(b) (6)	3.1	1790	99	6	4	NS	0.3(+)
095301	(b) (6)	11.8	987	NORM	100		NS	
095301	(b) (6)	2.7	1294	FEVER	35	10	LC	10.7(+)
095301	(b) (6)	1.0	1115	99	40	16	LC	19.0(+)
095301	(b) (6)	2.9	276	NORM	42	4	LC	2.8(+)
095301	(b) (6)	1.5	1726	100	8	8	NS	1.4(+)
095301	(b) (6)	1.0	1698	NORM	47	20	NS	3.6(+)
095301	(b) (6)	3.4	1246	100	96	52	LC	0.3(+)
095301	(b) (6)	1.8	356	FEVER	40	7	LC	1.0(+)
095301	(b) (6)	3.0	355	NORM	102	33	LC	2.0(+)
095301	(b) (6)	3.3	1647	99	27	7	NS	6.8(+)
095301	(b) (6)	6.1	511	NORM	34		LC	8.4(+)
096501	(b) (6)	2.8	468	NORM	10		LC	13.2(+)
096501	(b) (6)	6.1	421	98	100	20	LC	2.9(+)
096501	(b) (6)	2.8	1574	NORM	36		LC	1.6(+)
096501	(b) (6)	4.3	955	101	243		LC	3.6(+)
096501	(b) (6)	1.3	1250	FEVER	27	2	LC	21.8(+)
096501	(b) (6)	2.4	825	FEVER	21		LN	23.5(+)
096501	(b) (6)	2.8	740	103	33	3	LC	2.3(+)
096501	(b) (6)	1.8	1495	102	20	20	NS	2.8(+)
096501	(b) (6)	6.7	119	NORM	50	20	NS	1.0(+)
096501	(b) (6)	1.7	93	99	10	3	LC	1.1(+)
096501	(b) (6)	4.0	1132	NORM	37	5	NS	5.5(+)
096501	(b) (6)	3.9	1829	NORM	131	16	NS	6.8(+)
096501	(b) (6)	6.8	1086	NORM	12		LC	2.2(+)
096501	(b) (6)	3.1	755	100	15	3	NS	10.4(+)

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TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL-007 DOSE(PFU)=1000 LOT=CR319 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
096501	(b) (6)	1.7	308	101	66	50	LC	2.0(+)
096501		1.6	1086	NORM	56		NS	2.7(+)
096501		1.6	722	102	3	1	LN	2.7(+)
096501		1.0	1386	NORM	96	59	NS	10.0(+)
096501		2.5	1033	FEVER	25		LC	0.7(+)
096601		2.3	710	NORM	12	6	NS	5.9(+)
096601		2.3	1154	NORM	25		NS	5.9(+)
096601		2.1	657	NORM	16		NS	1.8(+)
096601		4.1	80	100	35		LN	2.3(+)
096601		1.0	625	NORM	2		NS	19.2(+)
096601		5.0	90	NORM	3		NS	7.3(+)
096601		4.1	1379	NORM	35	2	NS	11.1(+)
096901		10.3	823	101	182	59	LC	1.0(+)
096901		2.1	756	NORM	18	13	NS	4.9(+)
096901		2.3	571	97	159	50	NS	4.7(+)
096901		1.8	605	NORM	89	5	NS	
096901		1.8	1415	99	35	7	LC	6.7(+)
096901		3.8	377	102	225	225	LC	3.9(+)
096901		3.2	1139	99	210	60	NS	1.5(+)
096901		3.2	1487	98	103	2	LC	3.9(+)
096901		3.1	368	NORM	10		NS	5.3(+)
096901		1.3	984	NORM	13	5	LC	21.5(+)
096901		3.8	370	100	85	10	LC	4.0(+)
096901		1.2	124	102	100		LC	0.3(-)
097201		3.1	561	NORM	14	2	LC	12.6(+)
097201		3.3	1128	NORM	18	1	NS	21.0(+)
097201		2.9	1287	99	523	50	LC	0.7(+)
097201		2.1	1204	NORM	30		NS	10.0(+)
097201		1.0	1622	98	49	6	LC	16.0(+)
097201		3.7	762	NORM	25	5	LC	0.8(+)
097201		5.4	741	101	35		NS	0.3(+)
097201		1.3	1786	99	30		NS	22.5(+)
097201		1.2	1762	NORM	25	15	NS	11.5(+)
097201		4.0	1727	101	60		NS	5.0(+)
097201		1.8	1013	99	44	1	LC	23.6(+)
097201		1.5	981	99	24		LN	13.2(+)

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1140 LOT=CR452 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GP/ELISA
095301	(b) (6)	6.3	1249	NORM	16		LC	15.4(+)
095301		5.4	896	NORM	25		LC	23.5(+)
095301		1.9	1809	100	100	25	NS	1.9(+)
095301		1.6	1558	98	23	4	LC	19.0(+)
095301		1.8	787	99	47	23	LC	16.0(+)
095301		1.3	1570	100	193	92	LC	3.0(+)
095301		3.2	485	NORM	50	5	NS	7.6(+)
095301		1.3	1537	NORM	40	10	LC	8.3(+)
095301		4.3	664	FEVER	183	104	LC	1.5(+)
095301		3.2	311	104	4	4	LC	4.6(+)
095301		5.6	308	NORM	15	3	LC	2.4(+)
095301		1.8	381	99	25		LC	15.2(+)
095301		10.4	65	NORM	50	10	NS	3.7(+)
095301		1.5	1040	NORM	19		LC	23.0(+)
095301		2.5	413	NORM	57	4	LC	1.4(+)
095301		1.8	827	99	29	19	NS	13.6(+)
095301		1.8	1468	100	54	10	LC	19.0(+)
095301		1.8	1775	NORM	100		NS	13.5(+)
095301		1.1	513	NORM	74		LN	13.7(+)
095301		3.5	46	96	28	21	LN	
095301		3.9	994	99	20		LC	7.8(+)
095301		3.4	1375	102	500	500	LC	0.3(-)
095301		1.6	1561	98	142		LC	6.7(+)
095301		5.1	330	98	53	11	LS	1.5(+)
095301		3.8	771	98	75	39	LC	2.5(+)
095301		7.0	1000	98	12		LC	5.7(+)
095301		1.9	1262	100	21	3	NS	14.5(+)
095301		1.6	280	NORM	34	3	LC	1.3(+)
096501		3.7	76	NORM	5		LC	20.0(+)
096501		3.7	1248	NORM	9		LC	20.0(+)
096501		3.9	479	102	40	30	NS	0.8(+)
096501		5.2	431	102	51	1	LC	5.3(+)
096501		3.7	1188	NORM	41	9	LC	5.8(+)
096501		3.7	492	NORM	5		LN	5.8(+)
096501		1.3	1236	100	418	20	NS	6.6(+)
096501		3.6	1142	NORM	41		LC	19.5(+)
096501		2.1	1446	102	66	14	NS	2.9(+)
096501		2.5	692	100	51	25	LC	23.2(+)
096501		1.6	719	FEVER	15	13	LN	1.7(+)
096501		3.5	1036	100	62	16	LC	5.2(+)
096501		6.0	491	FEVER	60		LC	0.3(-)
096501		9.4	1151	NORM	68		LN	226.5(+)
096501		7.3	721	FEVER	15	13	LN	0.8(+)
096501		5.8	1480	NORM	15		PR	13.2(+)
096601		5.4	532		10		LN	38.5(+)
096601		5.0	89		30		NS	1.8(+)

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS-PROD PROTOCOL-007 DOSE(PFU)=1140 LOT=CR452 -----

(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
096601	(b) (6)	10.8	592	99	20	10	NS	1.9(+)
096901		4.6	1119	NORM	181	161	LC	1.3(+)
096901		8.9	77	FEVER	34	20	LC	0.3(-)
096901		10.3	698	102	98	90	LC	1.8(+)
096901		1.3	888	NORM	340		LC	7.5(+)
096901		5.1	288	NORM	238	208	LC	2.1(+)
096901		8.9	1163	FEVER	137	90	LC	3.1(+)
096901		2.3	672	NORM	30		NS	2.6(+)
096901		4.0	877	101	90		LC	1.0(+)
096901		9.4	1089	FEVER	500	500	LC	1.0(+)
096901		6.9	968	100	72	21	LC	2.8(+)
096901		1.4	451		12		NS	1.8(+)
096901		2.3	1119	NORM	99	20	LC	5.2(+)
096901		5.8	718	101	500	400	LC	
096901		1.3	103	NORM	10	10	LC	19.0(+)
096901		1.9	597	NORM	51	51	NS	3.7(+)
096901		8.8	93	NORM	86	23	LS	
096901		1.6	1126	101	148	143	LC	
096901		2.1	384	NORM	15		NS	1.4(+)
097201		4.5	967	102	34		LC	21.8(+)
097201		2.0	1291	101	60	2	LC	3.4(+)
097201		4.8	245	100	90		LC	1.6(+)
097201		4.1	1566	NORM	20		NS	2.8(+)
097201		12.0	73	99	70	8	NS	0.3(+)
097201		2.1	1913	NORM	16		NS	10.2(+)
097201		1.7	1419	99	34	11	NS	12.7(+)
097201		3.7	731	NORM	300	100	LC	4.5(+)
097201		1.3	456	FEVER	100	30	NS	10.2(+)
097201		2.7	483	NORM	37	2	NS	6.7(+)
097201		3.6	1164	99	131	23	LN	21.7(+)
097201		8.1	277	102	5		LC	7.0(+)
097201		1.1	1016	100	30		NS	19.1(+)
097201		1.4	665	NORM	6		LS	17.4(+)
097501		1.1	1409	NORM	>500	>500	NS	6.9(+)
097501		1.9	1536	NORM	110	50	NS	1.0(+)
097501		1.8	781	NORM	3		NS	2.5(+)
097501		1.8	193	FEVER	25	25	NS	0.7(+)
097501		1.9	1183	101	10		NS	2.1(+)
097501		1.7	708	NORM	50		NS	0.9(+)
097501		1.8	379	NORM	68	3	LS	3.5(+)
097501		1.8	958	NORM	36		LC	1.5(+)
097501		1.6	357	FEVER	>100	>100	NS	3.6(+)
097501		1.2	1294	NORM	30	15	NS	4.6(+)
097501		1.6	1009	FEVER	35		LC	0.9(+)
097501		1.3	609	NORM	14		NS	4.0(+)

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1140 LOT=CR452 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
097501	(b) (6)	1.4	466	NORM	20		NS	6.4(+)
097501		1.7	1017		UNK	UNK	NS	3.5(+)
097501		1.7	763	NORM	3		LC	10.3(+)
097501		1.8	460	NORM	6	6	LC	1.1(+)
097501		1.3	43	NORM	3	2	NS	20.3(+)

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1145 LOT=CR562 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
095301	(b) (6)	3.3	459	99	29	3	LC	21.6(+)
095301		1.0	1439	NORM	13	2	LC	18.0(+)
095301		1.9	758	NORM	8		LC	17.8(+)
095301		3.8	1263	99	100	50	NS	2.7(+)
095301		1.9	1896	97	46	27	NS	17.1(+)
095301		2.5	910	NORM	50	10	LC	5.9(+)
095301		5.8	803	NORM	30	15	LC	3.5(+)
095301		2.5	1862	FEVER	15	15	NS	11.3(+)
095301		5.1	1084	100	18	12	LC	32.0(+)
095301		1.3	1002	NORM	46	5	LC	8.0(+)
095301		1.6	1345	98	90	42	LC	15.8(+)
095301		4.3	362	102	40	5	NS	2.2(+)
095301		4.9	348	99	15	2	LC	1.4(+)
095301		6.3	1170	99	22	4	LC	3.7(+)
095301		3.2	1068	101	20	5	LC	4.0(+)
095301		1.0	1671	NORM	146	40	LC	5.8(+)
095301		1.5	1058	NORM	83	27	LC	2.9(+)
095301		3.2	65	NORM	15	10	NS	7.3(+)
095301		1.2	1456	NORM	33	5	LC	9.0(+)
095301		1.3	827	100	37	6	NS	10.5(+)
095301		1.9	1745	99	17	8	NS	10.5(+)
095301		1.3	1651	NORM	18	4	LC	24.3(+)
095301		1.9	1101	99	12	3	LC	4.9(+)
095301		3.0	343	NORM	87	12	LC	0.9(+)
095301		2.8	1769	NORM	29	15	NS	11.3(+)
095301		1.0	1429	NORM	UNK		NS	2.0(+)
095301		1.6	1449	100	27	7	NS	8.8(+)
095301		1.0	1352	100	18	6	LC	1.4(+)
095301		1.0	581	99	77	10	LC	16.4(+)
095301		1.0	1308	99	21	1	LC	6.7(+)
095301		1.0	1393	FEVER	42	12	LC	15.1(+)
095301		2.9	514	NORM	30		NS	0.8(+)

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1145 LOT=CR562 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
095301	(b) (6)	5.3	1664	NORM	42	2	NS	3.5(+)
096501		3.2	885	101	18	2	LN	8.8(+)
096501		2.9	463	FEVER	60		NS	3.8(+)
096501		1.9	951	NORM	42	18	LC	7.7(+)
096501		5.8	1447	NORM	287	61	LC	0.3(-)
096501		2.3	1551	NORM	8	8	LC	7.3(+)
096501		4.5	685	NORM	11	5	LC	13.4(+)
096501		8.1	797	FEVER	11		LN	0.3(-)
096501		1.8	1229	99	513	351	NS	6.1(+)
096501		6.6	396	NORM	11	5	LN	3.0(+)
096501		2.9	394	NORM	8	2	LC	47.5(+)
096501		3.8	1487	NORM	9	5	PR	16.5(+)
096501		3.3	997	100	23	2	NS	17.8(+)
096501		1.9	1496	NORM	24		NS	14.9(+)
096501		3.6	1351	NORM	43	2	LC	24.1(+)
096501		3.6	1446	103	12		LC	8.9(+)
096501		7.6	506	102	40	10	LC	2.1(+)
096501		10.7	287	NORM	20		LC	1.1(+)
096501		5.8	1479	NORM	17		PR	4.7(+)
096601		2.2	384		UNK		NS	
096601		1.4	1444	99	10	6	NS	5.6(+)
096601		3.7	625	NORM	10	2	NS	7.5(+)
096601		6.3	608	NORM	100	30	QN	0.3(+)
096601		1.5	1617	NORM	5		NS	78.0(+)
096601		4.0	1212	104	25	1	NS	1.0(+)
096601		4.4	555	FEVER	6	2	NS	8.4(+)
096601		11.5	560	FEVER	300	150	NS	2.5(+)
096601		3.4	213	NORM	200	40	NS	0.3(+)
096601		2.1	809	NORM	150	30	NS	3.5(+)
096601		3.6	843	NORM	22	12	NS	47.5(+)
096601		1.6	794	NORM	35	15	NS	7.1(+)
096901		10.5	1070	103	17	17	LC	0.3(+)
096901		2.8	1117	100	63	15	LC	7.4(+)
096901		5.0	765	NORM	110	55	LC	3.1(+)
096901		6.2	44	FEVER	36	21	LC	2.8(+)
096901		2.3	1183	NORM	36	23	LC	7.4(+)
096901		7.3	682	NORM	79	24	LC	1.5(+)
096901		5.7	1191	99	135	40	LC	5.4(+)
096901		12.6	63	NORM	122	49	LC	0.7(+)
097001		10.9	1083	104	100	100	NS	
097001		10.9	1395	NORM	82	4	LC	
097001		1.1	442	99	9		LN	
097001		3.7	1228	100	21	17	NS	
097001		4.8	1616	NORM	32		NS	
097001		1.3	1348	99	44	4	NS	

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1145 LOT=CR562 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GP/ELISA
097101	(b) (6)	1.7	1191	NORM	26	6	NS	7.8(+)
097101	(b) (6)	1.9	796	NORM	10	10	NS	16.3(+)
097101	(b) (6)	1.1	853	NORM	25	5	NS	8.6(+)
097101	(b) (6)	5.4	294	100	38	18	LC	1.3(+)
097101	(b) (6)	2.6	1495	FEVER	40		NS	11.3(+)
097201	(b) (6)	1.1	761	NORM	88	10	LC	1.5(+)
097201	(b) (6)	1.6	851	101	6		LC	4.7(+)
097201	(b) (6)	2.8	762	99	18		LC	14.5(+)
097201	(b) (6)	4.8	1512	100	653	54	LC	0.3(-)
097201	(b) (6)	1.2	319	NORM	31		NS	9.6(+)
097201	(b) (6)	1.4	378	NORM	8		NS	102.0(+)
097201	(b) (6)	6.1	1177	99	21	7	LC	4.1(+)
097201	(b) (6)	2.1	1558	101	47	12	LC	6.1(+)
097201	(b) (6)	6.6	249	NORM	30		LC	0.8(+)
097201	(b) (6)	5.7	1335		15		LC	2.1(+)
097501	(b) (6)	1.3	552	NORM	2	2	NS	1.4(+)
097501	(b) (6)	1.6	1259	99	6		NS	0.8(+)
097501	(b) (6)	1.7	804	NORM	8		LC	1.9(+)
097501	(b) (6)	1.8	784	NORM	10	2	NS	2.7(+)
097501	(b) (6)	1.8	193	FEVER	50	50	LC	0.3(-)
097501	(b) (6)	1.8	516	NORM	5	5	NS	4.6(+)
097501	(b) (6)	1.6	1309	NORM	35	20	NS	1.2(+)
097501	(b) (6)	1.8	366	NORM	101	45	NS	0.3(+)
097501	(b) (6)	1.6	57	NORM	60		NS	0.3(+)
097501	(b) (6)	1.6	624	NORM	250	250	LC	1.5(+)
097501	(b) (6)	1.8	1507	NORM	19	5	NS	0.3(+)
097501	(b) (6)	1.4	586	NORM	7		LN	5.7(+)
097501	(b) (6)	1.7	879	NORM	3	2	NS	6.1(+)
097501	(b) (6)	1.2	692	NORM	40	6	NS	1.3(+)
097501	(b) (6)	1.9	423	NORM	100	10	LC	>25.0(+)
097501	(b) (6)	1.2	569	NORM	16	16	NS	3.3(+)
097501	(b) (6)	1.7	730	NORM	21	4	LS	4.3(+)
097501	(b) (6)	1.2	397	NORM	100	100	NS	2.0(+)
097501	(b) (6)	1.9	1134		2	2	NS	7.6(+)
097601	(b) (6)	3.1	572	101	17	5	LC	
097601	(b) (6)	4.8	587	NORM	31	3	NS	

TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL=007 DOSE(PFU)=1460 LOT=CR724 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
095301	(b) (6)	1.0	1549	NORM	34	2	NS	16.5(+)
095301		1.9	1032	NORM	39	6	LC	4.4(+)
095301		3.3	1113	NORM	125	50	NS	5.0(+)
095301		2.5	1675	FEVER	96	7	NS	62.3(+)
095301		5.2	335	101	32	3	LC	4.3(+)
095301		2.7	1043	101	50	18	LC	9.2(+)
095301		4.7	1084	100	73	23	LC	21.0(+)
095301		1.5	1701	100	UNK		LS	9.2(+)
095301		4.0	362	NORM	55	17	LC	1.6(+)
095301		1.8	923	100	32	2	LC	2.5(+)
095301		1.4	1045	NORM	50		LC	25.0(+)
095301		4.5	1333	101	68	26	LC	3.1(+)
095301		1.0	1711	98	149	28	NS	4.6(+)
095301		1.0	1364	FEVER	45	20	LC	9.4(+)
095301		4.0	1625	NORM	90	10	NS	2.8(+)
095301		1.3	264	NORM	100	25	LC	4.3(+)
095301		4.7	367	NORM	22	4	LC	4.7(+)
095301		4.6	659		30	10	NS	1.8(+)
096301		2.0	318	NORM	40	40	LC	21.8(+)
096301		5.0	463	NORM	14		NS	2.6(+)
096301		2.8	632	NORM	10	10	NS	12.4(+)
096301		3.5	708	NORM	16	4	NS	7.6(+)
096301		7.6	253		30	30	NS	
096301		1.8	234		30	30	NS	
096501		1.8	1675	NORM	17	17	NS	19.9(+)
096501		3.2	318	99	25	5	LC	5.2(+)
096501		1.8	325	NORM	13	12	NS	8.4(+)
096501		4.7	1666	NORM	70	16	NS	20.3(+)
096501		1.7	691	NORM	47	16	LC	1.6(+)
096501		4.4	729	101	12		LC	13.7(+)
096601		4.0	710	NORM	12	4	NS	32.5(+)
096601		2.3	192		4		NS	4.5(+)
096801		2.4	647	NORM	50	50	LC	3.7(+)
096801		3.6	1109	NORM	100	100	NS	6.2(+)
096801		1.1	1272		10	10	LC	6.1(+)
096801		1.0	1074	NORM	3	3	NS	7.6(+)
096801		4.1	602	NORM	21	21	NS	0.3(+)
096801		6.0	916	NORM	30	10	LC	49.4(+)
096801		1.8	1539	NORM	27	20	NS	5.3(+)
096801		7.0	319	98	1	1	LN	128.5(+)
096801		5.8	194	FEVER	8	8	LC	2.1(+)
096801		9.6	189	NORM	200	200	NS	0.3(-)
096901		1.7	1224	99	42	12	NS	4.1(+)
096901		10.1	1558	100	450	100	LC	1.1(+)
096901		1.2	398	NORM	19	1	NS	5.7(+)
096901		3.8	814	NORM	76	37	LC	16.8(+)

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TABLE 1 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PROD PROTOCOL-007 DOSE(PFU)=1460 LOT=CR724 -----
(continued)

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
096901	(b) (6)	4.3	386	NORM	197	197	NS	0.3 (-)
096901		1.4	1104	102	36	22	LC	18.6 (+)
096901		4.4	417	NORM	23	23	LC	1.8 (+)
096901		2.0	1155	101	258	183	LC	1.0 (+)
096901		2.9	53	NORM	24		NS	13.8 (+)
096901		4.6	674	NORM	86	40	LC	18.2 (+)
096901		1.0	1342	NORM	7	2	NS	16.0 (+)
096901		8.0	984	NORM	20	6	LC	19.4 (+)
096901		2.2	547	NORM	16	2	LC	8.6 (+)
096901		1.0	1428	99	13		LC	10.4 (+)
097001		4.5	848	101	60		LC	
097001		2.2	713	99	50	50	NS	
097001		3.3	1606	NORM	20		NS	
097201		1.1	1507	NORM	20		NS	73.5 (+)
097201		1.3	1700	FEVER	18		NS	23.8 (+)
097201		3.5	1336	99	24	3	LC	3.5 (+)
097201		2.2	1386	98	20		NS	24.0 (+)
097401		1.4	1440	NORM	14		NS	11.7 (+)
097401		3.0	1382	NORM	74	1	NS	4.4 (+)
097401		3.4	616	FEVER	34	5	NS	
097401		4.3	516	NORM	12		LC	
097401		1.1	1244	NORM	70	1	NS	3.5 (+)
097401		3.0	1276	NORM	14	2	NS	9.6 (+)
097401		7.1	1224	FEVER	27		NS	15.2 (+)
097401		4.9	196	102	250	118	NS	
097401		5.8	166	FEVER	16	3	LC	1.7 (+)
097401		4.8	413	NORM	3	2	LC	4.7 (+)
097401		2.4	1127	NORM	21	1	NS	4.6 (+)
097401		7.6	764	102	182	22	LC	1.0 (+)
097401		1.4	1067	NORM	47		NS	1.0 (+)
097401		1.0	780	FEVER	11		NS	0.3 (-)

TABLE 3 (CONT.)
LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - POST REVACCINATION

----- LOTS=PROD PROTOCOL=007 REVACCINATION DOSE(PFU)=1460 REVACCINATION LOT=CR724 -----

STUDY	CASE	AGE (YRS)	LOT INJECTION 1	DOSE(PFU) INJECTION 1	DAY OF ONSET RELATIVE TO REVACCINATION	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
097201	(b) (6)	3.3	CR562	1145	571	101	40		NS	0.7(-)
095301		4.1	CR724	1460	938	FEVER	15	15	NS	0.3(+)
096501		6.0	CR724	1460	752	FEVER	12		LC	0.3(-)
097401		3.3	CR724	1460	194	NORM	6	5	NS	1.0(+)
097401		4.3	CR724	1460	402	NORM	21		NS	0.3(-)

----- LOTS=PROD PROTOCOL=007 REVACCINATION DOSE(PFU)=1625 REVACCINATION LOT=CR647 -----

STUDY	CASE	AGE (YRS)	LOT INJECTION 1	DOSE(PFU) INJECTION 1	DAY OF ONSET RELATIVE TO REVACCINATION	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
095301	(b) (6)	3.9	CR647	1625	1047	99	15		LC	0.3(-)
096901		2.4	CR647	1625	882	102	78	45	LC	0.7(+)
096901		1.1	CR647	1625	891	FEVER	440	340	LS	0.3(-)
096901		1.1	CR647	1625	1130	99	33	3	LN	1.3(+)
097401		2.0	CR647	1625	159	NORM	28	1	NS	1.0(+)

TABLE 3 (CONT.)
 LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
 HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - POST REVACCINATION

----- LOTS=PROD PROTOCOL=013 REVACCINATION DOSE(PFU)=1625 REVACCINATION LOT=CR647 -----

STUDY	CASE	AGE (YRS)	LOT INJECTION 1	DOSE(PFU) INJECTION 1	DAY OF ONSET RELATIVE TO REVACCINATION	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
099901	(b) (6)	2.7	CR647	54	241	98	15	4	LC	
099901		3.6	CR647	54	653	NORM	17	3	LC	0.3 (-)
099901		2.7	CR647	54	527	98	42	2	NS	0.3 (-)
099901		1.3	CR647	162	1078	103	268	147	LC	0.3 (-)
099901		3.4	CR647	162	1025	NORM	7	2	NS	0.3 (-)
099201		1.3	CR647	1625	1007	100	85		NS	0.3 (+)

TABLE 3 (CONT.)
 LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
 HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - POST REVACCINATION

----- LOTS=PROD PROTOCOL-014 REVACCINATION DOSE(PFU)=1625 REVACCINATION LOT=CR647 -----

STUDY	CASE	AGE (YRS)	LOT INJECTION 1	DOSE(PFU) INJECTION 1	DAY OF ONSET RELATIVE TO REVACCINATION	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
099701	(b) (6)	1.0	CR647	1625	1061	98	13	5	LC	0.9(+)
100501		3.0	CR647	1625	387	NORM	90		LC	0.3(+)

TABLE 3 (CONT.)
 LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
 HEALTHY CHILDREN 1-12 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - POST REVACCINATION

----- LOTS=PROD PROTOCOL-018 REVACCINATION DOSE(PFU)=1230 REVACCINATION LOT=CT683 -----

STUDY	CASE	AGE (YRS)	LOT INJECTION 1	DOSE(PFU) INJECTION 1	DAY OF ONSET RELATIVE TO REVACCINATION	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
101401	(b) (6)	5.0	CV336	260	489	99	119	70	NS	0.3 (-)
101401		2.6	CV336	260	366	98	48	24	LC	0.3 (-)

TABLE 4
LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY ADOLESCENTS AND ADULTS >= 13 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PRODUCTION (1987) PROTOCOL=007 DOSE(PFU)=1460 LOT=CR724 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
096301	(b) (6)	15.0	353	NORM	25	5	LC	0.3

----- LOTS=PRODUCTION (1987) PROTOCOL=007 DOSE(PFU)=1625 LOT=CR647 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
096901	(b) (6)	13.0	385		200	200	LS	1.3

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TABLE 4 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY ADOLESCENTS AND ADULTS >= 13 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PRODUCTION (1987) PROTOCOL=008 DOSE(PFU)=1140 LOT=CR452 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
098301	(b) (6)	19.0	235		70	9	LC	5.8
098301		26.0	686		250	50	NS	4.5
098401		31.0	281		100	50	LC	.
098401		37.0	734		19	3	LC	1.3
098401		26.0	1042		12	12	LC	2.5
098401		27.0	1015	NORM	104	53	LC	2.8
098501		34.0	912		75	75	LC	3.55
098501		32.0	318		200	200	LC	3.75
901301		33.0	709		60		LN	16.85

----- LOTS=PRODUCTION (1987) PROTOCOL=008 DOSE(PFU)=1145 LOT=CR562 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
098301	(b) (6)	38.0	181	NORM	36	24	LC	1.8
098301		24.0	655		600	50	LC	10.6
098401		29.0	405	NORM	130	10	LC	0.3
098401		31.0	1022		113	19	LC	7.1
098401		30.0	856	NORM	20	20	LC	4.9
098701		25.0	400				LC	1.6

----- LOTS=PRODUCTION (1987) PROTOCOL=008 DOSE(PFU)=2925 LOT=CR563 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
098301	(b) (6)	37.0	416	NORM	50	25	LC	1.9

----- LOTS=PRODUCTION (1987) PROTOCOL=008 DOSE(PFU)=3010 LOT=CR320 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
098301	(b) (6)	22.0	393	NORM	100		NS	2.2
098401		34.0	101	NORM	24		LC	0.9
098401		22.0	749		351	281	LC	2.6

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TABLE 4 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY ADOLESCENTS AND ADULTS \geq 13 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=PRODUCTION (1987) PROTOCOL=008 DOSE(PFU)=3265 LOT=CR453 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GP/ELISA
098301	(b) (6)	28.0	555		40	5	NS	1.2
098301		31.0	412		104	50	QN	4.7

4-17953

TABLE 4 (CONT.)

LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
HEALTHY ADOLESCENTS AND ADULTS >= 13 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RESEARCH (1982-83) PROTOCOL-001 DOSE(PFU)=950 LOT=CK472 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
084501	(b) (6)	16.0	995	NORM	26		NS	1.4
084501		15.0	2347		109	56	NS	0.9

TABLE 4 (CONT.)
 LISTING OF VARICELLA CASES GREATER THAN 42 DAYS POST FIRST INJECTION OF LIVE VARICELLA VACCINE (OKA/MERCK)
 HEALTHY ADOLESCENTS AND ADULTS \geq 13 YEARS OF AGE REGARDLESS OF INITIAL SEROSTATUS - ONE DOSE REGIMEN

----- LOTS=RESEARCH (1982-83) PROTOCOL=002 DOSE(PFU)=44 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
078101	(b) (6)	33.0	1898		500	300	QN	.
078101	(b) (6)	23.0	881		200	100	NS	.

----- LOTS=RESEARCH (1982-83) PROTOCOL=002 DOSE(PFU)=870 LOT=CH198 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
078101	(b) (6)	20.0	1361		100	3	NS	.

----- LOTS=RESEARCH (1982-83) PROTOCOL=002 DOSE(PFU)=1400 LOT=CG798 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
090101	(b) (6)	30.0	157	NORM	1	1	LC	.
090101	(b) (6)	32.0	713	NORM	58		LC	.

----- LOTS=RESEARCH (1982-83) PROTOCOL=002 DOSE(PFU)=2750 LOT=CL308 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
082601	(b) (6)	23.0	679		40	40	NS	.

----- LOTS=RESEARCH (1982-83) PROTOCOL=002 DOSE(PFU)=3500 LOT=CL805 -----

STUDY	CASE	AGE (YRS)	DAY OF ONSET RELATIVE TO INJECTION 1	MAX TEMP (ORAL, F)	NO. OF LESIONS	NO. OF VESICLES	SERO/ CULTURE	6 WEEK GPELISA
088101	(b) (6)	25.0	299		20	3	PR	.