SCALING Per Protocol population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.75	2.93	2.67	2.83
Day 15	1.18	2.14	1.57	2.00
Day 29	0.75	2.14	1.17	1.83
Change from baseline	- 2.00	- 0.79	- 1.50	- 1.00
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0588		0.0151	

SCALING Patients with score of 0 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	29 (51%)	2 (7%)	21 (36%)	4 (14%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0433		0.1342	

SCALING Patients with score of 0 or 1 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	45 (79%)	7 (25%)	36 (62%)	11 (38%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0415		0.0655	

ERYTHEMA Per Protocol population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.49	2.79	2.48	2.59
Day 15	1.28	2.32	1.52	2.17
Day 29	0.81	2.11	1.22	2.00
Change from baseline	- 1.68	- 0.68	- 1.26	- 0.59
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0035		0.0227	

ERYTHEMA Patients with score of 0 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	24 (42%)	2 (7%)	16 (28%)	1 (3%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0009	0.0085		0.1197	

ERYTHEMA Patients with score of 0 or 1 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	46 (81%)	6 (21%)	38 (66%)	11 (38%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0215		0.0924	

PLAQUE THICKNESS Per Protocol population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.63	2.61	2.55	2.66
Day 15	0.98	2.00	1.62	2.10
Day 29	0.44	1.86	1.10	1.97
Change from baseline	- 2.19	- 0.75	- 1.45	- 0.69
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0052		0.0001	

PLAQUE THICKNESS Patients with score of 0 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	40 (70%)	4 (14%)	24 (41%)	5 (17%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0304		0.0026	

PLAQUE THICKNESS Patients with score of 0 or 1 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	50 (88%)	7 (25%)	37 (64%)	8 (28%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0028		0.0043	

COMPOSITE PSORIASIS SCORE Per Protocol population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	7.88	8.32	7.71	8.07
Day 15	3.44	6.46	4.71	6.28
Day 29	2.00	6.11	3.50	5.79
Change from baseline	- 5.88	- 2.21	- 4.21	- 2.28
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0070		0.0017	

COMPOSITE PSORIASIS SCORE Patients with score of 0 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	18 (32%)	2 (7%)	14 (24%)	1 (3%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0141	0.0164		0.4107	

COMPOSITE PSORIASIS SCORE Patients with score of 0 or 1 at endpoint Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	33 (58%)	2 (7%)	20 (34%)	2 (7%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0077		0.0152	

The results for the ITT population were as follows.

SCALING ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.73	2.88	2.67	2.81
Endpoint	0.92	2.16	1.19	1.87
Change from baseline	- 1.81	- 0.72	- 1.48	- 0.94
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0337		0.0848	

SCALING Patients with score of 0 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	30 (47%)	2 (6%)	22 (35%)	4 (13%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0285		0.2076	

SCALING Patients with score of 0 or 1 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	47 (73%)	8 (25%)	39 (62%)	11 (35%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0271		0.1873	

ERYTHEMA ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.48	2.69	2.48	2.58
Endpoint	0.94	2.13	1.30	2.03
Change from baseline	- 1.55	- 0.56	- 1.17	- 0.55
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0042		0.0399	

ERYTHEMA Patients with score of 0 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	26 (41%)	2 (6%)	16 (25%)	1 (3%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0003	0.0091		0.0896	

ERYTHEMA Patients with score of 0 or 1 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	48 (75%)	6 (19%)	39 (62%)	11 (35%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0271		0.1292	

PLAQUE THICKNESS ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.63	2.59	2.54	2.65
Endpoint	0.61	1.84	1.14	2.00
Change from baseline	- 2.02	- 0.75	- 1.40	- 0.65
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0036		0.0008	

PLAQUE THICKNESS Patients with score of 0 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	42 (66%)	5 (16%)	25 (40%)	5 (16%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0330		0.0044	

PLAQUE THICKNESS Patients with score of 0 or 1 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	52 (81%)	8 (25%)	39 (62%)	8 (26%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0019		0.0186	

COMPOSITE PSORIASIS SCORE ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	7.84	8.16	7.68	8.03
Endpoint	2.47	6.13	3.63	5.90
Change from baseline	- 5.38	- 2.03	- 4.05	- 2.13
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0049		0.0094	

COMPOSITE PSORIASIS SCORE Patients with score of 0 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 at endpoint	19 (30%)	2 (6%)	14 (22%)	1 (3%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0088	0.0177		0.4192	

COMPOSITE PSORIASIS SCORE Patients with score of 0 or 1 at endpoint ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 0 or 1 at endpoint	35 (55%)	2 (6%)	20 (32%)	2 (6%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0084		0.0121	

b. Investigators' global assessment of response.

The results for the Per Protocol population were as follows.

INVESTIGATOR'S GLOBAL EVALUATION Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Completely clear	25 (44%)	2 (7%)	16 (28%)	2 (7%)
Almost clear	16 (28%)	4 (14%)	11 (19%)	4 (14%)
Marked improvement	4 (7%)	1 (4%)	3 (5%)	2 (7%)
Moderate improvement	4 (7%)	2 (7%)	12 (21%)	3 (10%)
Slight improvement	6 (11%)	6 (21%)	5 (9%)	5 (17%)
No change	1 (2%)	11 (39%)	10 (17%)	9 (31%)
Worse	1 (2%)	2 (7%)	1 (2%)	4 (14%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0015		0.0062	

INVESTIGATORS GLOBAL EVALUATION Patients with score of 1 or 2 at endpoint* Per Protocol population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 1 or 2 at endpoint	41 (72%)	6 (21%)	27 (47%)	6 (21%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0211		0.0078	
* 1 = completely clear 2 = almost clear				

The results for the ITT population were as follows.

INVESTIGATOR'S GLOBAL EVALUATION ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Completely clear	26 (41%)	2 (6%)	16 (25%)	2 (6%)
Almost clear	17 (27%)	4 (13%)	13 (21%)	4 (13%)
Marked improvement	4 (6%)	1 (3%)	4 (6%)	2 (6%)
Moderate improvement	4 (6%)	2 (6%)	12 (19%)	3 (10%)
Slight improvement	6 (9%)	8 (25%)	5 (8%)	5 (16%)
No change	5 (8%)	12 (38%)	11 (17%)	11 (35%)
Worse	2 (3%)	3 (9%)	2 (3%)	4 (13%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0010		0.0230	

INVESTIGATORS GLOBAL EVALUATION Patients with score of 1 or 2 at endpoint* ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Score of 1 or 2 at endpoint	43 (67%)	6 (19%)	29 (46%)	6 (19%)
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
< 0.0001	0.0133		0.0202	
* 1 = completely clear 2 = almost clear				

c. Secondary efficacy variables. The scalp pruritus scores, the extent of scalp involvement, and the patient's assessment of the response are provided only for the ITT population, as follows.

Pruritus scores ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	2.61	2.50	2.71	2.45
Endpoint	0.91	1.59	1.19	1.74
Change from baseline	- 1.70	- 0.91	- 1.52	- 0.71
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0016	0.0040		0.3302	

Extent of scalp involvement ITT population				
Mean values	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Baseline	4.00	3.88	3.79	3.94
Endpoint	2.30	3.47	2.90	3.52
Change from baseline	- 1.70	- 0.41	- 0.89	- 0.42
p values				
BMV foam vs vehicle foam	BMV lotion vs placebo lotion		BMV foam vs BMV lotion	
0.0001	0.0386		0.0007	

Patient's global evaluation ITT population				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
Completely clear	26 (41%)	2 (6%)	15 (24%)	1 (3%)
Almost clear	20 (31%)	4 (13%)	14 (22%)	3 (10%)
Marked improvement	5 (8%)	5 (16%)	13 (21%)	5 (16%)
Moderate improvement	4 (6%)	3 (9%)	8 (13%)	4 (13%)
Slight improvement	0	10 (31%)	5 (8%)	5 (16%)
No change	7 (11%)	7 (22%)	8 (13%)	11 (35%)
Worse	2 (3%)	1 (3%)	0	2 (6%)

p values		
BMV foam vs vehicle foam	BMV lotion vs placebo lotion	BMV foam vs BMV lotion
0.0001	0.0001	0.0171

4) Safety evaluation.

The incidence of adverse events which were judged to be possibly, probably, or definitely related to treatment in the BMV foam group, and the incidence of these events in the BMV foam vehicle group, were as follows.

Incidence of adverse events possibly, probably, or definitely related to treatment		
	BMV foam	Vehicle foam
# pts	63	32
Paresthesia	1 (2%)	1 (3%)
Pruritus	1 (2%)	0
Psoriasis	1 (2%)	1 (3%)
Acne	1 (2%)	0
Alopecia	1 (2%)	0
Conjunctivitis	1 (2%)	0

All of the above adverse events in the BMV foam group were classified as mild in severity.

The results of the application experience query were as follows.

Incidence and severity of local burning/itching/stinging at Day 15 and 29				
	BMV foam	Vehicle foam	BMV lotion	Placebo lotion
# pts	63	32	63	30
Day 15				
Within 30 min				
None	28 (48%)	11 (37%)	32 (52%)	15 (52%)
Mild	25 (43%)	11 (37%)	25 (40%)	10 (34%)
Moderate	5 (9%)	6 (20%)	4 (6%)	2 (7%)
Severe	0	2 (7%)	1 (2%)	2 (7%)
After 30 min				
None	56 (97%)	30 (100%)	60 (97%)	27 (93%)
Mild	2 (3%)	0	1 (2%)	2 (7%)
Moderate	0	0	1 (2%)	0
Severe	0	0	0	0
Day 29				
Within 30 min				
None	42 (68%)	13 (41%)	47 (75%)	17 (57%)
Mild	17 (27%)	11 (34%)	13 (21%)	8 (27%)
Moderate	2 (3%)	4 (13%)	3 (5%)	4 (13%)
Severe	1 (2%)	4 (13%)	0	1 (3%)
After 30 min				
None	61 (98%)	32 (100%)	61 (97%)	26 (87%)
Mild	1 (2%)	0	2 (3%)	2 (7%)
Moderate	0	0	0	1 (3%)
Severe	0	0	0	1 (3%)

The total incidence of local burning/itching/stinging, and the incidence according to the maximum severity were as follows.

Total incidence and severity of local burning/itching/stinging				
Product	Total incidence	Maximum severity		
		Mild	Moderate	Severe
BMV foam n=63	34 (54%)	28 (44%)	5 (8%)	1 (2%)
BMV lotion n=63	33 (52%)	26 (41%)	6 (10%)	1 (2%)
Vehicle foam n=32	24 (75%)	13 (41%)	7 (22%)	4 (12%)
Placebo lotion n=30	20 (67%)	12 (40%)	5 (17%)	3 (10%)

Two patients were prematurely discontinued from the study for adverse events that were considered to be treatment related; these were worsening of the psoriasis in one patient on the vehicle foam, and a rash of the face and ears in one patient on the placebo lotion.

Reviewer's comments: In summary, for the clinical signs the data were analyzed as a) the change in mean scores from baseline, b) the percentages of patients with a score of 0 at endpoint, and c) the percentages of patients with a score of 0 or 1 at endpoint. This was done for scaling, erythema, plaque thickness, and the composite psoriasis score. The comparative analyses were BMV foam vs the vehicle foam; BMV foam vs BMV lotion, and BMV lotion vs the placebo lotion. Results for the evaluable (per protocol population) were as follows.

For scaling, BMV foam was significantly superior to the foam vehicle in the change in mean scores from baseline, and in the percentages of patients with a score of 0 and with a score of 0 or 1 at endpoint. BMV foam was not significantly different from BMV lotion in the percentages of patients with a score of 0 or a score of 0 or 1 at endpoint, and was significantly superior to BMV lotion in the change in mean scores from baseline. BMV lotion was not superior to the placebo lotion in the change in mean scores from baseline, and was marginally superior to the placebo lotion in the percentages of patients with a score of 0 or a score of 0 or 1 at endpoint.

For erythema, BMV foam was significantly superior to the foam vehicle in the change in mean scores from baseline, and in the percentages of patients with a score of 0 and with a score of 0 or 1 at endpoint. BMV foam was not significantly different from BMV lotion in the percentages of patients with a score of 0 or a score of 0 or 1 at endpoint, and was significantly superior to BMV lotion in the change in mean scores from baseline. BMV lotion was superior to the placebo lotion in all three parameters.

For plaque thickness, BMV foam was significantly superior to the foam vehicle in the change in mean scores from baseline, and in the percentages of patients with a score of 0 and with a score of 0 or 1 at endpoint. BMV foam was significantly superior to BMV lotion in the change in mean scores from baseline, and in the percentages of patients with a score of 0 or a score of 0 or 1 at endpoint. BMV lotion was superior to the placebo lotion in all three parameters.

For the composite psoriasis scores, BMV foam was significantly superior to the foam vehicle in the change in mean scores from baseline, and in the percentages of patients with a score of 0 and with a score of 0 or 1 at endpoint. BMV foam was significantly superior to BMV lotion in the change in mean scores from baseline and in the percentages of patients with a score of 0 or 1 at endpoint, and was not significantly different from BMV lotion in the percentages of patients with a score of 0 at baseline. BMV lotion was superior to the placebo lotion in all three parameters.

In the physician's global assessment of response, BMV foam was significantly superior to the vehicle foam and to BMV lotion in the overall global assessment, and in the percentage of patients that had a score of 1 or 2 (cleared or almost cleared) at endpoint.

Adverse events were primarily local burning, itching, and stinging, which was mild in most patients, moderate in a few patients, and severe in one patient.

Other clinical studies

1. Phase I study - Evans Medical. This study was performed to evaluate the tolerance to repeated doses of the BMV mousse (foam) formulation when applied to the scalps of 24 normal subjects. Applications of an amount approximately equivalent to 3.5 gm betamethasone valerate were made twice daily for 7 days. Blood samples were taken within 30 minutes pre-dose and at 2 hours post-dosing on days 1, 4, and 7.

Adverse events which were considered to be probably drug-related were pruritus in three subjects. The analysis of serum cortisol levels did not indicate any treatment effect.

2. Phase II study - Evans Medical. This study, performed in the UK, was a double blind, multicenter comparison of betamethasone valerate mousse (foam) with a placebo in patients with scalp psoriasis. Fifty patients were treated with applications twice daily for 28 days.

The primary efficacy variables were scores for erythema, scaling and plaque elevation, graded on a scale of from 0 to 4. Safety evaluations included morning serum cortisol levels at each return visit.

The analysis of the change from baseline in the mean scores for clinical signs was as follows.

Clinical signs scores (means)			
Visit	BMV foam	Placebo foam	p value
Erythema			
Baseline	2.2	1.9	0.1800
Endpoint	0.8	1.6	0.0001
Change	- 1.6	- 0.4	0.0001
Plaque elevation			
Baseline	2.5	2.1	0.0442
Endpoint	0.8	1.5	0.0126
Change	- 1.7	- 0.6	0.0019
Scaling			
Baseline	2.7	2.4	0.1092
Endpoint	1.0	1.8	0.0059
Change	- 1.7	- 0.5	0.0035

Local adverse events were stinging in 16 (70%) of the foam group and 10 (40%) of the vehicle group; tenderness in 3 on the foam and 4 on the vehicle, and itching in 11 patients in each group.

Mean values for serum cortisol levels did not change notably in either treatment group, and no patients in the BMV foam group had a cortisol value below 5.0 ug/dL.

Labeling review

Ths sponsor's draft labeling of 7/21/98 has been reviewed by this medical officer and is appended.

Summary and evaluation

As was agreed in meetings between the Division and the sponsor, the following studies have been provided to demonstrate the safety and efficacy of Betamethasone Valerate Foam 0.1%: a vasoconstrictor assay, an HPA axis suppression study, and a multicenter, controlled study in patients with psoriasis.

In the vasoconstrictor assay BMV foam was shown to have a potency intermediate between that of a marketed BMV lotion and BMV ointment. In the HPA axis suppression study no suppression was found with application of 15 gm of BMV foam twice daily for 7 days to areas of dermatitic skin comprising 30% of the body surface area in patients with psoriasis and atopic eczema.

The clinical effectiveness study was a multicenter, double blind, randomized comparison of BMV foam with the foam vehicle, a marketed BMV lotion, and a placebo lotion in patients with moderate to severe scalp psoriasis. Applications of the test products were made BID to the scalp for 28 days. The efficacy parameters were a grading of scaling, erythema, and plaque thickness on a scale of from 0 to 4, and an investigator's global evaluation as one of seven categories of change from baseline.

For the clinical signs, results were that BMV foam was significantly superior to the vehicle foam in the change in mean scores from baseline, in the percentage of patients with a score of 0 at endpoint, and in the percentage of patients with a score of 0 or 1 at endpoint, for scaling, erythema, plaque thickness, and a composite score. BMV foam was either significantly superior to, or was not significantly different from, BMV lotion in the change in mean scores from baseline, in the percentage of patients with a score of 0 at endpoint, and in the percentage of patients with a score of 0 or 1 at endpoint, for scaling, erythema, plaque thickness, and a composite score.

In the physician's global evaluation of response, BMV foam was significantly superior to the foam vehicle and to BMV lotion, both in the overall assessment and in the percentage of patients that were cleared or almost cleared at endpoint.

Adverse events were primarily local burning, itching, and stinging, which were mild in most patients, and moderate in a few patients.

It is felt that the product, 0.1% betamethasone valerate foam, is approvable for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. This is the same indication as the comparator product, Valisone lotion, and the currently marketed E. Fougera's 0.1% betanethasone valerate lotion. In vasoconstriction studies, 0.1% betamethasone valerate foam was less potent than 0.1% betamethasone valerate ointment, and appeared to be equipotent to 0.1% betamethasone valerate lotion. In an HPA axis suppression study which was performed in accordance with Division guidance on protocol and trial design, there was no HPA axis suppression with 0.1% betamethasone valerate foam.

Conclusions: It is felt that the studies provided in the NDA adequately demonstrate the safety and effectiveness of BMV foam for the proposed labeling indication.

Recommendations: It is recommended that this NDA for Betamethasone Valerate Foam 0.1% be approved for the labeling indication 'For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses'.

/S/

Phyllis A. Huene, M.D.

Cc: Orig NDA
HFD-540
HFD-540/Huene
HFD-540/Cintron
HFD-540/Jacobs
HFD-540/DeCamp

SW 12/14/98

10/19/98