Redacted according to Section 40, FOI Act

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **1. STUDIES ON TOLERABILITY, ABSORPTION AND TISSUE LEVELS** (1 of 4 pages)	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Subjects Sex (M/F) Mean Age	Test Materials	**Results**	**Adverse Events** (Drug-related)
Z,1	SFF 101 [redacted] 1 centre in USA	Plasma concentrations and metabolite before and after Lamisil® 1% solution applied once daily for 7 days.	11 healthy volunteers 3/8 32 yrs	Lamisil® 1% soln.	No relevant concentrations of either Lamisil® (SF 86-327) or metabolite (SDZ 86-621) were observed in plasma.	None
Z, 109	SFF 103 [redacted] 1 centre in USA	Plasma concentrations and metabolite before and after Lamisil® 1% solution applied once daily for 7 days.	10 pats. with tinea cruris 10/0 38 yrs	Lamisil® 1% soln.	Plasma concentrations of Lamisil® (SF 86-327) and metabolite (SDZ 86-621) were at the borderline of the limit of detection of the assay i.e. 4.8 ng/ml and 5.1 ng/ml resp..	None
8, 1	SF 0058 [redacted] 1 centre in USA	Cumulative irritation potential, using 6 occlusive patches over 14 days, according to defined scoring system.	28 healthy volunteers 10/18 44.9 yrs	SF 86-327 1% solution SF 86-327 2% solution SF 86-327 3% solution Vehicle soln.	Significant irritation was elicited at 4th, 5th or 6th readings for all test substances which created a relatively low cumulative irritation index. Approx. 20% manifested cumulative irritation by endpoint.	Peeling occurred in some vols. for all test materials.

Soln = Solution, pats = patients, vols = volunteers

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APPEND IX 1.

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Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **1. STUDIES ON TOLERABILITY, ABSORPTION AND TISSUE LEVELS** (2 of 4 pages)	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Subjects Sex (M/F) Mean Age	Test Materials	**Results**	**Adverse Events** (Drug-related)
8, 108	SFF 102 [redacted] 1 centre in USA	Cumulative irritation potential, using 9 occlusive and 9 semi-occlusive patches over 21 days, according to defined scoring system.	25 healthy volunteers 17/8 38.8 yrs	SF 86-327 1% soln. SF 86-327 2% soln. SF 86-327 3% soln. Vehicle soln. Vehicle "N" Tap water	No significant cumulative irritation was elicited by any test materials. The highest values were noted under occlusion in the marketed control substance, vehicle "N".	None
8, 64	SFF 701 [redacted] 1 centre in USA	Cumulative irritation potential, using 9 occlusive and 9 semi-occlusive patches over 21 days, according to defined scoring system.	25 healthy volunteers 1/24 41.5 yrs	Lamisil® vehicle soln. Water Clotrimazole 1% soln. Vehicle "N" soln.	Negligible cumulative irritation was elicited by Lamisil® vehicle solution, water and clotrimazole 1% solution. Vehicle "N" was a mild irritant.	None

Soln = Solution

Appendix 1.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **1. STUDIES ON TOLERABILITY, ABSORPTION AND TISSUE LEVELS** (3 of 4 pages)	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Subjects Sex (M/F) Mean Age	Test Materials	**Results**	**Adverse Events** (Drug-related)
8, 1[redacted]	SFF 107 1 centre in USA	Part I Phototoxicity potential i.e. wheal and flare response, using patches for 24 hrs followed by UVA irradiation	10 healthy volunteers 6/4 42.2 yrs	Lamisil® 2% soln. Lamisil® vehicle soln. Clotrimazole 1% soln. Vehicle "N"	None of the test materials was considered to induce a contact dermal phototoxic response.	None
8, 214		Part II Contact photoallergy potential using Repeated Insult Patch Test plus irradiation. Induction phase - 2 patches for 24 hrs 3 X per week for 3 weeks. Challenge phase 2 weeks later.	31 healthy volunteers 10/21 48.4 yrs	Lamisil® 2% solution Lamisil® vehicle soln. Clotrimazole solution Vehicle "N" solution	None of the tested solutions was considered to induce contact photoallergy in humans.	None
8, 273		Part III Contact irritation and/or allergic sensitisation using Repeated Insult Patch Test- as above, no irradiation.	192 healthy volunteers 65/127 38 yrs	Lamisil® 2% solution Lamisil® vehicle soln. Clotrimazole solution Vehicle "N" solution	None of the tested solutions was considered to induce contact dermal sensitisation in humans.	None

Soln = Solution

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **1. STUDIES ON TOLERABILITY, ABSORPTION AND TISSUE LEVELS** (4 of 4 pages)	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Subjects Sex (M/F) Mean Age	Test Materials	**Results**	**Adverse Events** (Drug-related)
N/A	SFF Tol. Japan 1 centre	Skin irritation potential - erythema and oedema following closed patch test and photosensitivity patch test for 24 hours.	24 healthy volunteers 18/6 26 yrs	Lamisil®-HCl 1% solution Lamisil®-HCl vehicle soln. Lamisil®-HCl Cream econazole 1% soln. bifonazole 1% soln. butenafine-HCl soln. tolnaftate 2% soln. ethanol purified water	Erythema in 4 patients with Lamisil® 1% solution, in 1 patient with vehicle, in 3 patients with econazole, in 3 patients with ethanol, in 3 patients with water and in 2 patients with blank control. Skin sensitisation was not observed. Photo-irritation and photosensitisation were not observed.	Not available
7, 226 & 283	SFF 307 [redacted] 1 centre in UK	Skin pharmacokinetics derived from terbinafine concentrations in sequential skin surface biopsies following a single application or once daily application over 7 days.	36 healthy volunteers 18/18 19-59 yrs	Lamisil® 1% Solution as: Spray or Dropper dispenser Lamisil® 1% Cream	All 3 forms showed comparable skin pharmacokinetics when applied for 7 days	None

Soln = Solution

Annex IX 1.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **2. SUMMARY OF COMPLETED EFFICACY TRIALS**	(for National Authority use)

Study	Design	Duration (Test drug)	Country	Total No. Pats.Enrolled	Lamisil®		Comparator	
					Enrolled	ITT	Enrolled	ITT
T. pedis								
SFF 104	d-b placebo	2 weeks	USA	86	43	36	43	39
SFF 301	d-b placebo	1 week	DK/F/UK/Iceland	172	115	71	57	39
SFF 351	d-b placebo	1 week	USA	153	104	58	49	28
SFF 309	d-b clotrimazole	1,4 weeks	D/Czechia	699	348	217	351	212
T. corporis/cruris								
SFF 105	d-b placebo	1 week	USA	66	32	26	34	26
SFF 108	d-b placebo	1 week	Brazil	72	36	35	36	35
SFF 303	d-b placebo	1 week	F/CH/N	151	102	72	49	37
Candidosis								
SFF 306	d-b placebo	1 week	Mexico	132	86	69	46	38
SFF 311	d-b placebo	1 week	Central America	134	94	93	40	39
Pityriasis versicolor								
SFF 305	d-b placebo	1 week	NL/B	115	79	76	36	34
SFF 353	d-b placebo	1 week	USA	152	103	97	49	47
Seb. dermatitis								
SFF 106	open-label	4 weeks	S	22	22	21	n/a	n/a
SFF 304	d-b placebo	2 weeks	USA/CDN	80	40	40	40	39
SFF 352	d-b placebo	2 weeks	USA/CDN	80	39	38	41	40
Dermatomycoses	open-label	2 or 4 weeks	Japan	112	112	106	n/a	n/a
			TOTAL	2,226	1,355	1,055	871	653

ITT = Intention to treat population; n/a = not applicable
SFF 309 - Lamisil® group received 1 week Lamisil®, 3 weeks placebo; clotrimazole group received 4 weeks clotrimazole

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Appendix 2.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **3.1. PLACEBO-CONTROLLED TRIALS in TINEA PEDIS (1 Week Treatment once/twice daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1 Week	Follow-up*	1 Week	Follow-up*	
9, 1	SFF 301 [redacted] 15 centres in DK, I, F, UK. **(once daily)**	Effective = negative microscopy and culture (mycological cure), sum of signs and symptoms severity score for erythema (E), pruritis (P) and desquamation (D) ≤2, individual severity scores for E,P,D ≤1 and individual severity scores for pustules, vesiculation and incrustation =0.	Lamisil® 71 (51:20) 41 yrs Placebo 39 (35/4) 42 yrs	Lamisil® 34/69 (49%) Placebo 5/37 (14%) p=0.002	Lamisil® 60/71 (85%) Placebo 9/39 (23%) P<0.001	Lamisil® 14/69 (20%) Placebo 2/37 (5%) P=0.049	Lamisil 54/71 (76%) Placebo 8/39 (21%) P<0.001	There were no serious AEs or discontinuations for AEs. 7 (6%) of subjects in the Lamisil® group and 6 (11%) in the placebo group had skin and appendage disorders.
10, 1	SFF 351 [redacted]. 10 centres in USA. **(twice daily)**		Lamisil® 58 (47/11) 41 yrs Placebo 28 (18/10) 43 yrs	Lamisil® 24/56 (43%) Placebo 4/28 (14%) p=0.008	Lamisil® 51/58 (88%) Placebo 4/28 (14%) p<0.001	Lamisil® 10/56 (18%) Placebo 1/28 (4%) P=0.085	Lamisil® 38/58 (66%) Placebo 1/28 (4%) P<0.001	There were no serious AEs or discontinuations for AEs. None of the AEs reported were considered to be drug related.

Significance determined by Cochran Mantel-Haenszel test comparing Lamisil® vs. placebo
* Follow-up = last post-baseline observation up to and including Week 8.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **3.1. PLACEBO-CONTROLLED TRIALS in TINEA PEDIS (2 Weeks Treatment once daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				2 Weeks	Follow-up*	2 Weeks	Follow-up*	
12, 1	SFF 104 [redacted] 4 centres in USA	Mycological cure = negative microscopy and culture. Effective = sum of "complete cure" (mycological cure plus no signs and symptoms) and "cure" (mycological cure plus no more than 2/6 mild signs and symptoms)	Lamisil® 36 (27/9) 37 yrs Placebo 39 (26/13) 41 yrs	Lamisil® 28/36 (78%) Placebo 8/39 (21%) p<0.001	Lamisil® 36/36 (100%) Placebo 9/39 (23%) P<0.001	Lamisil® 18/36 (50%) Placebo 5/39 (13%) P<0.001	Lamisil 31/36 (86%) Placebo 6/39 (15%) P<0.001	There were no serious AEs or discontinuations for AEs. 2 subjects on Lamisil® reported burning/stinging on application and 1 developed inter-tarsal dermatitis. No AEs were reported for placebo.

Significance determined by Fisher's exact test comparing Lamisil® vs. placebo
* Follow-up = last post-baseline observation up to and including Week 6.

Appendix 2.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **3.2. CONTROLLED TRIALS WITH CLOTRIMAZOLE in TINEA PEDIS** **(1,4 Weeks Active Treatment twice daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1, 4 Wks	Follow-up*	1,4 Wks	Follow-up*	
11, 1	SFF 309 [redacted] 35 centres in Germany, 5 in Czech Republic	Mycological cure = negative microscopy and culture. Effective = sum of "complete cure" (mycological cure plus no signs and symptoms) and "cure" (mycological cure plus signs and symptoms score ≤2)	Lamisil® 1 week 217 (150/67) 47 yrs Clotrimazole 4 weeks 212 (147/65) 45 yrs	Lamisil® 1 week 89/206 (43%) Clo # 4 weeks 87/204 (43%) p=0.635	Lamisil® 1 week 199/216 (92%) Clo # 4 weeks 193/212 (91%) p=0.411	Lamisil® 1 week 30/211 (14%) Clo # 4 weeks 28/205 (14%) p=0.857	Lamisil® 1 week 181/217 (83%) Clo # 4 weeks 174/212 (82%) p=0.649	There were no serious AEs. One subject in the Clo# group discontinued for an application site reaction. 13 (4%) subjects in the Lamisil® group and 11 (3%) in the clotrimazole group reported skin and appendage disorders.

Lamisil® group received 1 week Lamisil® and 3 weeks placebo; clotrimazole group received 4 weeks clotrimazole. Both groups were followed up for a further 4 weeks.
Significance determined by Cochran Mantel-Haenszel test comparing Lamisil® vs. placebo
Clo = clotrimazole
* Follow-up = last post-baseline observation up to and including week 8 or later

Appendix 2

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **4. PLACEBO-CONTROLLED TRIALS In TINEA CORPORIS/CRURIS (1 Week Treatment once daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1 Week	Follow-up*	1 Week	Follow-up*	
12, 131	SFF 105 [redacted] 3 centres in USA	For all studies: Primary: Mycological cure = negative microscopy and culture. Effective = sum of "complete cure" (mycological cure plus no signs and symptoms) and "cure" (mycological cure and no more than 2/6 mild signs and symptoms)	Lamisil® 26 (17/9) 41 yrs Placebo 26 (18/8) 44 yrs	Lamisil® 10/26 (38%) Placebo 6/26 (23%) P=0.368	Lamisil® 18/26 (69%) Placebo 6/26 (23%) p=0.002	Lamisil® 5/26 (19%) Placebo 2/26 (8%) P=0.419	Lamisil 17/26 (65%) Placebo 2/26 (8%) p<0.001	There were no serious AEs or discontinuations due to an AE. One subject in each group experienced an application site reaction.
12, 262	SFF 108 [redacted] 3 centres in Brazil		Lamisil® 35 (26/9) 32 yrs Placebo 35 (23/12) 37 yrs	Lamisil® 15/32 (47%) Placebo 5/34 (15%) p<0.001	Lamisil® 25/33 (76%) Placebo 10/35 (29%) p<0.001	Lamisil® 9/33 (27%) Placebo 2/35 (6%) p=0.021	Lamisil® 22/34 (65%) Placebo 7/35 (20%) p<0.001	There were no serious AEs or discontinuations due to an AE. There were no drug-related AEs.

Significance determined by Fisher's exact test comparing Lamisil® vs placebo.
*Follow-up = last post-baseline observation up to and including Week 4.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **4. PLACEBO-CONTROLLED TRIALS In TINEA CORPORIS/CRURIS (1 Week Treatment once daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1 Week	Follow-up*	1 Week	Follow-up*	
13, 1	SFF 303 [redacted] 20 centres in F, N, CH.	Mycological cure = negative microscopy and culture. Effective = mycological cure plus sum of severity scores for erythema, desquamation and pruritis ≤2.	Lamisil® 72 (56/16) 42 yrs Placebo 37 (28/9) 45 yrs	Lamisil® 54/69 (78%) Placebo 4/36 (11%) P<0.001	Lamisil® 61/72 (85%) Placebo 10/36 (28%) p<0.001	Lamisil® 26/69 (38%) Placebo 0/36 (0%) P<0.001	Lamisil 51/72 (71%) Placebo 4/36 (11%) p<0.001	There were no serious AEs or discontinuations due to an AE. 3 (3%) subjects in the Lamisil® group and 2 (4%) in the placebo group experienced an application site reaction.

Significance determined by the Cochran-Mantel-Haenszel test comparing Lamisil® vs placebo.
*Follow-up = last post-baseline observation up to and including Week 8.

Appendix 2.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **5. PLACEBO-CONTROLLED TRIALS in PITYRIASIS VERSICOLOR (1 Week Treatment twice daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1 week	Follow-up*	1 week	Follow-up*	
14, 1	SFF 305 [redacted] 22 centres in NL, 10 in B.	For all studies: Mycological cure = negative microscopy Effective = microscopic cure and total signs and symptom score (sum of erythema, desquamation and pruritis) ≤1	Lamisil® 76 (39/37) 34 yrs Placebo 34 (20/14) 32 yrs	Lamisil® 26/68 (38%) Placebo 8/32 (25%) p=0.141	Lamisil® 58/73 (79%) Placebo 15/34 (44%) p<0.001	Lamisil® 20/72 (28%) Placebo 5/33 (15%) p=0.106	Lamisil® 52/74 (70%) Placebo 11/34 (32%) p<0.001	There were no serious AEs or discontinuations for AEs. 7/76 (9%) Lamisil® and 3/34 (9%) placebo patients experienced skin and appendage disorders.
15, 1	SFF 353 [redacted] 10 Centres in USA		Lamisil® 97 (47/50) 34 yrs Placebo 47 (26/21) 34 yrs	Lamisil® 57/96 (59%) Placebo 26/46 (57%) ns	Lamisil® 76/97 (78%) Placebo 14/47 (30%) p<0.001	Lamisil® 43/96 (45%) Placebo 13/46 (28%) p=0.047	Lamisil® 74/97 (76%) Placebo 13/47 (28%) p<0.001	There were no serious AEs or discontinuations for AEs. 1/97 (1%) subject in the Lamisil® group and 1/47 (2%) in the placebo group experienced skin and appendage disorders.

Significance determined by Cochran Mantel-Haenszl test comparing Lamisil® vs. placebo
* Follow-up = last post-baseline observation up to and including Week 8.

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Appendix 2.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **6. PLACEBO-CONTROLLED TRIALS In CANDIDOSIS (1 Week Treatment once daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Efficacy Results				All Adverse Events (AEs) (Drug-related i.e. possibly, probably, definitely)
				% Mycological Cure		% Effective Treatment		
				1 Week	Follow-up*	1 Week	Follow-up*	
17, 1	SFF 306 [redacted] al. 6 centres in Mexico	For all studies: Primary: Mycological cure = negative microscopy and culture. Effective = sum of "complete cure" (mycological cure plus no signs and symptoms) and "cure" (mycological cure and signs and symptoms score ≤2, and no pustules, encrustation or vesiculation)	Lamisil® 69 (32/37) 41 yrs Placebo 38 (20/18) 40 yrs	Lamisil® 40/68 (59%) Placebo 7/36 (19%) P<0.001	Lamisil® 34/68 (50%) Placebo 10/36 (28%) p=0.020	Lamisil® 27/69 (39%) Placebo 5/36 (14%) P=0.002	Lamisil® 32/69 (46%) Placebo 8/36 (22%) p=0.007	There were no serious AEs. Two subjects in each group discontinued for application site reactions. 24 (30%) subjects in the Lamisil® group and 17 (38%) in the placebo group experienced skin and appendage disorders.
16, 1	SFF 311 [redacted] 4 centres in Dominican Republic, Ecuador, Panama, Guatemala.		Lamisil® 93 (53/40) 43 yrs Placebo 39 (17/22) 47 yrs	Lamisil® 39/93 (42%) Placebo 11/39 (28%) P=0.073	Lamisil® 62/93 (66%) Placebo 22/39 (56%) P=0.229	Lamisil® 12/93 (13%) Placebo 0/39 (0%) P=0.016	Lamisil® 56/93 (60%) Placebo 16/39 (41%) P=0.043	There were no serious AEs. One Lamisil® subject discontinued for site application events. 7 (7.5%) subjects in the Lamisil® group and 2 (5%) in the placebo group experienced skin and appendage disorders.

Significance determined by Cochran-Mantel-Haenszel test comparing Lamisil® vs placebo.
*Follow-up = last post-baseline observation up to and including Week 8.

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APPENDIX 2

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **7. PLACEBO-CONTROLLED TRIALS In SEBORRHEIC DERMATITIS (2 Weeks Treatment once daily)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	% Effective Treatment		**All Adverse Events (AEs)** (Drug-related i.e. possibly, probably, definitely)
				2 Weeks	Follow-up*	
18, 214	SFF 352 [redacted] 4 centres in USA , 2 in CDN	For both studies: Effective = both scaling and erythema absent at all sites (cure) or scaling and erythema are minimal at ≤2 sites and absent at all other sites (marked improvement)	Lamisil® 39 (24/15) 43 yrs Placebo 40 (31/9) 43 yrs	Lamisil® 13/36 (36%) Placebo 14/37 (38%) P=0.850	Lamisil® 13/38 (34%) Placebo 13/40 (33%) P=0.873	There were no serious AEs.1 subject in the Lamisil® group and 2 in the placebo group discontinued because of dermatologic or application site reactions. 20.5% Lamisil® and 20% placebo patients reported skin and appendage disorders, 17.9% Lamisil® and 22.5% placebo patients reported application site disorders.
18, 1	SFF 304 [redacted] 4 Centres in USA, 2 in CDN		Lamisil® 40 (21/19) 50 yrs Placebo 40 (22/18) 51 yrs	Lamisil® 9/40 (23%) Placebo 6/39 (15%) P=0.467	Lamisil® 13/40 (33%) Placebo 14/39 (36%) P=0.731	There were no serious AEs or discontinuations for AEs. 3 (7.5%) of Lamisil® patients and 7 (17.5%) placebo patients reported skin and appendage disorders and/or apllication site reactions.

Significance determined by Cochran Mantel-Haenszel test comparing Lamisil® vs. placebo
* Follow-up = last post-baseline observation up to and including Week 8.

Name of Company: SANDOZ PHARMA Name of Product: Lamisil® 1% Solution Name of Active Ingredient: Terbinafine	SUMMARY OF CLINICAL TRIALS referring to Part IV of Dossier **8. NON-CONTROLLED TRIALS** **(2-4 Weeks Treatment)**	(for National Authority use)

Ref. Vol., page	Study No. Investigator Centre(s)	Diagnosis, Treatment Duration and Criteria for Evaluation	No. of Pats. Sex (M/F) Mean Age	Effective Treatment (%)		**Adverse Events (AEs)** (Drug-related i.e. possibly, probably, definitely)
				Week 4	Week 6	
17, 254	SEE 106 [redacted] 1 Centre in Sweden	**Seborrhoeic dermatitis of scalp - 4 weeks treatment once daily** "Effective" treatment based on a score combining area of scalp involvement and severity of infection.	22 (15/7) 35 yrs (safety population)	13/21 (62%)	13/21 (62%)	Mild dryness of skin (n=2) attributed to concomitant medication. No other AEs were reported.
N/A	2 Collaborative Japanese studies, 3 centres each.	**Dermatomycoses** Duration of treatment was 4 weeks, tinea pedis was 4 weeks. "Global efficacy rating" based on mycology and a clinical assessment rating scale.	Study 1 49 (28/21) 49 yrs Study 2 63 (36/27) 63 yrs	**EOS** Study 1 32/44 (73%)	**EOS** Study 2 47/62 (76%)	Study 1: 2 (4%) patients experienced mild irritation at application site. Study 2: 2 (3%) patients experienced an application site reaction causing one to discontinue. No other AEs were reported in the 2 studies.

EOS = End of study but time period not known.

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APPENDIX 2.