Appendix 14

Provisional Translation
from Japanese Original

May 15, 1998
Notification PSB No.447

The Standards Marketing Approval of Athlete's Foot and Ringworm Remedies

1 Scope of Athlete's Foot and Ringworm Remedies

The scope of preparations subject to these standards covers external medicines intended for the relief of symptoms associated with athlete's foot and ringworm Kampo medicine* formulas and non-Kampo crude drug remedies consisting of crude drug only are not covered).

*Kampo medicine is traditional Japanese medicine.

2 Approval Standards

The approval standards for athlete's foot and ringworm remedies are as follows. For preparations deviating from these standards, efficacy and safety data and reasons justifying the combination should be submitted; the preparation in question will be reviewed based on these data.

(1) Types of Active Ingredients

a. The types of active ingredients that may be combined are listed in Table 1.
b. At least 1 of the active ingredients from either Column I (apart from the ingredients in Groups 12 and 13) or Column II of Table 1 must be combined.
c. Active ingredients in different columns listed in Table 1 may be mutually combined.
d. When active ingredients from Column V of Table 1 are to be combined with other ingredients in the same Column, the use of only 1 ingredient is allowed.
e. Up to 3 active ingredients from Column I of Table 1 may be used. However, with the exception of undecylenic acid and zinc undecylenate in Group 1, the use of only 1 ingredient from each group is allowed. Active ingredients marked with "□" must not be combined with the other ingredients in this column.
f. When active ingredients from Group 1 of Column III or Group 1 of Column IV listed in Table 1 are to be combined, the use of only 1 ingredient from the same group is allowed.
g. Up to 3 active ingredients from Group 2 of Column III listed in Table 1 may be used. However, acetic acid should not be combined with the other ingredients in this group.
h. In Column VI, the combination of allantoin with aldioxa and the combination of glycyrrhizinic acid or its salts with glycyrrhetinic acid are not permitted. In Column VII, the combination of *d*-camphor with *dl*-camphor and the combination of mentha oil with *dl*-menthol and *l*-menthol are not permitted.

(2) Quantities of Active Ingredients

a. The maximum concentration of each of the active ingredients is shown in Table 1.
b. The minimum concentration of individual active ingredients listed in Column I (except for Groups 12 and 13) and Column II of Table 1 is 1/5th of the maximum

concentration (for ingredients with a concentration in parentheses, the minimum concentration is 1/5th of the one in the parentheses). In this case, the concentration of 1 or more ingredients must be at least half of the specified maximum concentration (for ingredients with concentrations in parentheses, the minimum concentration must be the one provided in parentheses).

c. The minimum concentration of individual active ingredients listed in Groups 12 and 13 of Column I and those listed in Columns III, IV, V, VI, VII, VIII, and IX of Table 1 is 1/10th of the maximum concentration. However, in the case of benzalkonium chloride in Group 1 of Column III, the concentration must be as listed in the maximum concentration column.

(3) Dosage Form

The dosage forms are aerosols, ointments, external liquids, and external powders.

(4) Dosage and Administration

Preparations should be applied to the skin surface several times a day. The method of application should be clearly indicated.

(5) Indications

The indications are to be within the scope of “athlete’s foot, jock itch, and ringworm.”

Table 1

Classification		Active ingredient	Maximum concentration (%)
Column I	Group 1	Undecylenic acid	10
		Zinc undecylenate	20
		□ Phenyl-11-iode-10-undecynoate	0.5
	Group 2	□ Exalamide	5
	Group 3	□ Clotrimazole	1
		□ Econazole nitrate	1
		□ Miconazole nitrate	1
		□ Tioconazole	1
	Group 4	□ Zinc diethyldithiocarbamate	25
	Group 5	□ Ciclopirox olamine	1
	Group 6	□ Siccanin	1 (potency)
		□ Trichomycin	15,000,000 units/100 g
		□ Pyrrolnitrin	0.5 (potency)
	Group 7	Thianthol	30
	Group 8	2,4,6-Tribromphenol caproate	2
	Group 9	Trimethylcetylammonium pentachlorophenate	2
	Group 10	□ Tolciclate	1
		Tolnaftate	2
	Group 11	□ Haloprogin	1
	Group 12	Sulfur	10
	Group 13	Hibiscus syriacus bark (converted to the crude drug amount)	10
Column II	Group 1	Salicylic acid	10 (2)
	Group 2	Zinc oxide	60 (2)
Column III	Group 1	Acrinol	0.2
		Alkylpolyaminoethyl glycine	1
		Berberine benzoate	0.5
		Isopropylmethylphenol	3
		Dequalinium chloride	0.5
		Benzalkonium chloride	0.05
		Benzethonium chloride	0.5
		Chlorhexidine hydrochloride	1
		Chlorhexidine gluconate solution	2.5
		Dequalinium acetate	1
		Hinokitiol	0.1
		Resorcin	5
	Group 2	Benzoic acid	12
		Chlorobutanol	1
		Acetic acid	2
		Phenol	2
		Iodine tincture	20

Column IV	Group 1	Diphenylpyraline hydrochloride	0.2
		Diphenhydramine hydrochloride	2
		Chlorpheniramine	0.5
		Diphenhydramine salicylate	2
		Diphenylimidazole	0.2
		Diphenhydramine	1
		Chlorpheniramine maleate	0.5
	Group 2	Crotamiton	10
Column V		Ethyl aminobenzoate	6
		Dibucaine hydrochloride	0.5
		Procaine hydrochloride	2
		Lidocaine hydrochloride	2.5
		Oxypolyethoxydodecane	3
		Dibucaine	0.5
		Lidocaine	2.5
Column VII	Group 1	Allantoin	1
		Aldioxa	0.2
		Ichthammol	6
		Glycyrrhizinic acid and its salts	1
		Glycyrrhetinic acid	1
		Methyl salicylate	2.5
		Dimethyl isopropylazulene	0.04
	Group 2	Lithospermum root (converted to the crude drug amount)	6
		Japanese angelica root (converted to the crude drug amount)	6
Column VII		*d*-Camphor	4
		dl-Camphor	4
		Thymol	2.5
		Mentha oil	0.5
		dl-Menthol	3
		l-Menthol	3
		d-Borneol	5
Column VIII		Urea	10
		Diethyl phthalate	25
Column IX		Aluminum hydroxychloride	10