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GENERAL DERMATOLOGY AND  
DERMATOLOGIC SURGERY  
MOHS' SURGERY FOR SKIN CANCER  
LASER SURGERY

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Dockets Management Branch  
Food and Drug Administration  
12420 Parklawn Drive, Rm 1-23  
Rockville, MD 20857

To whom it may concern:

Please find enclosed nominations for the following medications pursuant to FDAMA (Pub. L 105-115):

Clotrimazole-Hydrocortisone Cream  
Triamcinolone-Pramoxine Lotion  
Retinoic (Tretinoin) Acid Lotion  
Triamcinolone Ointment 0.5%  
Triamcinolone Cream 0.5%

Thank you very much for your assistance in this matter.

Sincerely,



Ira J. Berman, M.D.

Enclosures

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NOM 9

NOMINATION: TRIAMCINOLONE-PRAMOXINE HCL LOTION

Ingredient Name: Triamcinolone, Pramoxine HCL

Chemical Name: Triamcinolone Pramoxine HCL

Common Name: Triamcinolone Pramoxine HCL

Chemical Grade: USP

How Supplied: Powder

Information: USP

Safety Data: Triamcinolone (Aristocort) and Pramoxine HCL (Pramosone) are brand names of the chemicals. Please refer to their NDA (new drug application) for safety data.

Dosage Form: Triamcinolone 0.025%, Pramoxine HCL 1% in a lotion base

Route of Administration: Topical

Rationale: The two active ingredients work better together than separately. I have used this combination for over 10 years with excellent results. The combination that I use provides a better anti-inflammatory effect than commercially available products-these having only 1% hydrocortisone (Pramosone Lotion) or 2 ½% hydrocortisone (Pramosone 2 ½% Lotion). This combination has been reviewed in the dermatological literature with excellent results for non-intertriginous areas.

NOMINATION: CLOTRIMAZOLE-HYDROCORTISONE CREAM

Ingredient Name: Clotrimazole, Hydrocortisone

Chemical Name: Clotrimazole Hydrocortisone

Common Name: Clotrimazole Hydrocortisone

Chemical Grade: USP

How Supplied: Powder

Information: USP

Safety Data: Clotrimazole (Lotrimin) and Hydrocortisone (Hytone) are brand names of the chemicals. Please refer to their NDA (new drug application) for safety data.

Dosage Form: 1% Clotrimazole, 1% Hydrocortisone in a cream base

Route of Administration: Topical

Rationale: The two active ingredients work better together than separately. I have used this combination for over 10 years with excellent results. This combination is much safer than Lotrisone which has a medium-strength topical steroid which can cause significant side effects in the groin or flexural regions. The nominated combination has been extensively reviewed and praised in the dermatological literature.

NOMINATION: RETINOIC ACID (TRETINOIN) LOTION 0.05%

Ingredient Name: Retinoic Acid (Tretinoin)

Chemical Name: Retinoic Acid (Tretinoin)

Common Name: Retinoic Acid (Tretinoin)

Chemical Grade: USP

How Supplied: Powder

Information: USP

Safety Data: Retinoic Acid (Retin-A) is a brand name of the chemical. Please refer to their NDA (new drug application) for safety data.

Dosage Form: Retinoic Acid (Tretinoin) 0.05% in a lotion base

Route of Administration: Topical

Rationale: The base provides better results and better patient acceptance in a wide range of patients. Irritancy levels with the cream bases are unacceptable. The lotion base does not contain isopropyl myristate or mineral oil. I have used this lotion for over 10 years with excellent results and patient acceptance.

NOMINATION: TRIAMCINOLONE CREAM 0.5%

Ingredient Name: Triamcinolone

Chemical Name: Triamcinolone

Common Name: Triamcinolone

Chemical Grade: USP

How Supplied: Powder

Information: USP

Safety Data: Triamcinolone (Aristocort) is a brand name of the chemical. Please refer to its NDA (new drug application) for safety data.

Dosage Form: Triamcinolone 0.5% in a cream base

Route of Administration: Topical

Rationale: This formulation is very important in treating selective, highly-allergic patients in my practice. The cream is preservative-free. I have been using this formulation for over 10 years in my practice with excellent results. Preservatives are well-documented to cause problems in selective dermatological patients because of the patients' high degree of sensitivity.

NOMINATION: TRIAMCINOLONE OINTMENT 0.5%

Ingredient Name: Triamcinolone

Chemical Name: Triamcinolone

Common Name: Triamcinolone

Chemical Grade: USP

How Supplied: Powder

Information: USP

Safety Data: Triamcinolone (Aristocort) is a brand name of the chemical. Please refer to its NDA (new drug application) for safety data.

Dosage Form: Triamcinolone 0.5% in an ointment base

Route of Administration: Topical

Rationale: This formulation is very important in treating selective, highly-allergic patients in my practice. The ointment is preservative-free. I have been using this formulation for over 10 years in my practice with excellent results. Preservatives are well-documented to cause problems in selective dermatological patients because of the patients' high degree of sensitivity.

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