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Dockets Management Branch (HFA 305)
Food and Drug Administration
12420 Parklawn Drive Room 1-23
Rockville, MD 20857

RE: Docket No. 98N-0182

Dear Sir/ Madam:

I am writing to request that I be included as a physician able to purchase the listed bulk drugs in order to compound the following medications. None of the medications I compound are simply copies of commercially available products. All of my products have proven to be very cost effective for the patient. Each of the formulations listed below is compounded in my office for some of the listed reasons.

1. No comparable product exists in the current available medications.
2. The formulation, as prepared in my office is free of a common sensitizer present in commercial preparations.
3. A number of well-documented irritants that are present in commercial formulations have been eliminated from my products.
4. The concentration of one of the active ingredients has increased in our product in order to increase the therapeutic value.
5. Patients without prescription insurance save money because our products are consistently more economical.

Please consider the following substances: hydrocortisone, hydroquinone, clotrimazole, fluocinonide, salicylic acid, triamcinalone and tretinoin.

- BLEACHING COMPOUND – Kligman formula
 - 6 lbs. cream HR
 - 10 oz. hydroquinone powder
 - 2 oz. HC powder
 - 43.68 gm. powder retin A

This product is absolutely the most effective bleaching cream. Nothing available commercially is comparable. The efficacy of this formula has been well documented, as shown in the following sources:

1. Happer, R. (1979). Advance in topical therapy of skin diseases. MMW- Munch Medical-Wochenschr. Jan 26. 121(4): 141-4.
2. Kligman, A. & Willis, I. (1975). A new formula for depigmenting human skin. Arch-Dermatology. Jan. 111(1): 40-8.
3. Herzberg, J. (1985). Therapy of melanin induced pigment anomalies. Hautarzt. Nov. 36(11): 635-8.

- CLO H- clotrimazole hydrocortisone
 - 6 lbs. of cream base

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- 28.35 gm. clotrimazole
- 28.35 gm. Hydrocortisone

This product is used to treat inflammatory tinea in intertriginous areas. The addition of hydrocortisone decreases the amount of time it takes for the patient to recover symptomatically from inflammatory tinea. The strengths of the two active ingredients are actually OTC and therefore our producing this compound should not be an issue.

- EZ – 4% erythromycin with zinc (a hydroalcoholic vehicle)
 - 5 gallons of lotion base
 - 1 lb., 12 oz. of granular erythromycin
 - 14 gm of zinc

This product is not commercially available. The 4 % erythromycin is both anti-inflammatory and anti-androgenic, making it an excellent product for treating acne vulgaris. The addition of zinc increases the effectiveness of the erythromycin. 4% erythromycin, as opposed to the 2% commercially available, is vastly more effective. Besides acne, this product is useful as both axillary and pedal deodorant. I know of no other formulation capable of treating these conditions. The efficacy of a 4% erythromycin with zinc preparation is attested to in the following references:

1. Matschiner, S., Neubert.,R., & Wohlrab, W. (1995). Optimization of topical erythromycin formulations by ion pairing. Skin Pharmacology. 8(6): 319-25.
2. Pierard, G., Pierard- Franchimont, C. (1993). Effect of a topical erythromycin-zinc formulation on sebum delivery. Evaluation by combined photometric multi-step sampling with Sebutape. Clinical Exp Dermatopathology. Sept 18 (5): 410-3.
3. Korting, H., Kerscher, M., Schafer-Korting, M. & Bertchenbreiter, U. (1993). Influence of topical erythromycin preparations for acne vulgaris on skin surface pH. Clinical Investigation. Aug. 71(8): 644-8.
4. Sweren, R. (1991). A clinical trial comparing the safety and efficacy of a topical erythromycin-zinc formulation with a topical clindamycin formulation. Journal of American Academy of Dermatology. Apr. 24(4): 664-5.
5. Papa, C. (1991). Topical erythromycin and zinc for acne. Journal of American Academy of Dermatology. Feb. 24 (2 pt 1): 318-9.

- FLUO OINTMENT – similar to Lidex Ointment
 - 6 lb. cream base
 - 21.84 gm fluocinonide

This product is used whenever a class II potency topical steroid is required. The difference in our preparation is that it does not contain propylene glycol, a known sensitizer. The following references discuss the reasons for avoiding propylene glycol in selected patients.

Generics also use propylene glycol and this is the only way I can assure my patients of getting an effective product free of sensitizers and irritants.

1. Lahti, A., Poutiainen, A., & Hannuksela, M. (1993). Alcohol vehicles in tests for non-immunological immediate contact reactions. Contact Dermatitis. Jul. 24(1): 22-5.
2. Catanzaro, J., & Smith, J. (1991). Propylene glycol dermatitis. Journal of American Academy of Dermatology. Jan. 24(1): 90-5.
3. Funk, J., & Maibach, H. (1994). Propylene glycol dermatitis: re-evaluation of an old problem. Contact Dermatitis. Oct. 31(4): 236-41.

- HC 2.5% – strong hydrocortisone
 - 2.5 hydrocortisone
 - 6 lbs. of cream base

Again, the formulation used in my office is free of propylene glycol and is formulated for areas where a fluorinated steroid is contraindicated.

- PSORIASIS OINTMENT - for thick scaly psoriasis
 - 6 lbs. ointment base
 - 5 oz. salicylic acid
 - 1.362 gm. Fluocinonide

This product is not commercially available. It is used for very scaly psoriasis. Salicylic acid is a known keratolytic which is more effective when combined with a potent steroid.

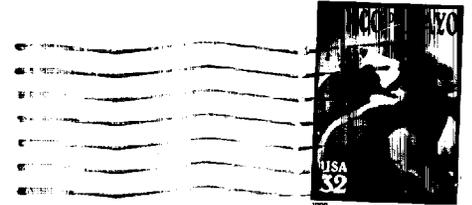
- TR. OINTMENT – triamcinalone ointment
 - 6 lbs. ointment
 - 43.68 grains triamcinalone powder

This steroid is used when a potency lower than that found with FLOU OINTMENT is required. It too is free of propylene glycol.

- TRET CREAM – tretinoin similar to “Retin A”
 - 6 lb. cream base R
 - .7, 1.42, or 2.8 grams of tretinoin -- depending on the strength

This formulation contains no alpha isopropyl myristate, a known irritant and sensitizer. Our product is therefore less drying than “Retin A”, though, not as greasy as “Renova”. In the several years that we have produced this product we have never had a patient return to “Retin A” after trying our product. The effectiveness of this product has been demonstrated by years of use in my patients. I have never had a patient request to be transferred back to Retin A after using this product. Numerous references attest to the problems of isopropyl myristate. There are no comparable products available in the full gamut of strengths without this irritant.

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