JERUSSI CONSULTING, INC.

3311 Midland Road
Fairfax, Virginia 22031 USA

Tel: 703-273-3903 • Fax: 703-293-9161

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June 17, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

Re: Citizen's Petition - Suitability Petition for a prescription drug product, Tri-Luma® NDA 21-112 containing fluocinolone acetonide, hydroquinone, and tretinoin cream as a Topical Solution.

FDA Dockets Management Branch:

Enclosed, please find a copy of a petition submitted pursuant to 21CFR 314.93 to the commissioner of the FDA by the undersigned. By this petition I request the Agency to permit the filing of an Abbreviated New Drug Application for a Topical solution of the three actives. fluocinolone acetonide, hydroquinone, and tretinoin (0.01%, 4%, and 0.05% w/w respectively) which is the current listed drug product as a topical cream Tri-Luma® NDA 21-112 held by the firm Hill Dermaceuticals, Inc. This drug product differs from the listed drug only in dosage form. The information described herein are: A.) Action requested, B.) Statement of grounds, C.) Environmental impact, D.) Economic impact, E.) Certification and Enclosures containing Labels and Labeling information.

Please contact me at the number listed above for questions and/or comments pertaining to this petition request.

Sincerely,

Robert A. Jerussi

Robert A. Jerussi, Ph.D.

2003P-0279

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SUITABILITY PETITION

Dear Sir/Madam:

Jerussi Consulting, Inc. ("Jerussi") submits this petition pursuant to 21 C.F.R. 10.25(a) and 10.30 and in accordance with the regulations at 21 C.F.R. 314.93 to request that the Commissioner of he Food and Drug Administration ("Commissioner") make a determination that a **topical solution** for the drug product NDA #21-112, Tri-Luma (cream), with no changes in active ingredients or strengths, for the treatment of Melanesia will be an acceptable dosage form substitution.

A. Action Requested

The petitioner requests that the Commissioner make a determination that Galderma product, Tri-Luma cream containing 0.01% Fluocinolone Acetonide, 4% Hydroquinone, and 0.05% Tretinoin can be formulated as a topical solution, and filed as an abbreviated New Drug Application referencing Tri-Luma as the Reference Listed Drug (RLD).

B. Statement of Grounds

The Orange Book lists the approval of Tri-Luma, Active Ingredients; Fluocinolone Acetonide; Hydroquinone; Tretinoin, at strengths 0.01%; 4%; 0.05% respectively as NDA #21112 to the applicant Hill Dermac. The dosage form approved and route of administration is a cream and topical. The plan is to develop the three active ingredients at the approved strengths in a topical solution where the formula will afford strength, applicability, and stability. Further, since the Waxman/Hatch 1984 law permits the substitution of a similar dosage form 314.161(a)(1), FDA must make a determination as to whether a listed drug is substitutable for reasons of safety or effectiveness before an ANDA using that listed drug as a RLD may be approved.

Tri-Luma Cream currently listed in the Orange Book, Attachment A, is an organic/aqueous based topical applied cream. The summary basis of approval for Tri-Luma indicates the chemistry, manufacturing, and controls required no additional studies, and further, since all three active pharmaceutical ingredients contained, are referenced to other products containing the active ingredients in topical administered dosages such as creams and topical solutions, e.g.,

Fluocinolone acetonide	Tretinoin
12787, Medicis (cream)	20438, Roche (oral)
13960, Medicis (ointment)	19049, 17522, 17340 Johnson & Johnson (cream)
15296, Medicis (solution)	17955, 17579, Johnson & Johnson (Gel)
16161, Medicis (cream)	16921, Johnson & Johnson (Solution)
19452, Hill (oil)	20475, Johnson & Johnson (μ-sphere gel)
20001, Hill (shampoo)	19963, Johnson & Johnson (emollient cream)
21112, Hill (cream)	20886, Ligand (gel)
	20400 Bertek (gel)
	20404 Bertek (gel)
	20922, Galderma (Solution)
	75264, 75265, 75213 Spear Pharm (Cream)
	75589, 75529 Spear Pharm. (Gel)
	74873, Copley (Solution)
	75260, Morton Grove (Solution)
	21112, Hill (Cream)

Hydroquinone is listed in the Orange Book for Tri-Luma (21112, Hill) at 4% and is available at concentrations of 1.5 or 2% under the Tentative Final Monograph for Skin Bleaching Drug Products. At higher concentration (3 or 4%), hydroquinone is an ingredient of prescription topical creams (ICN, Medicis), gel (ICN) and *solution* (Neutrogena)

Jerussi is submitting herewith, (see attachement B) Labeling for the RLD, Tri-Luma. Accompanying this Label is the proposed Label for the proposed product, Fluocinolone Acetanide (0.01%), Hydroquinone (4%), and Tretinoin (0.05%) Topical Solution (see Attachement C).

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 C.F.R. 25.31a, since the action requested will not increase the use of the active moieties. Therefore, an environmental assessment is not required for the requested action.

D. Economic Impact

Pursuant to 21 C.F.R. 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. Jerussi will promptly provide such information if so requested.

E. Certification

Jerussi certifies that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Robert A. Jerussi

Robert A. Jerussi, Ph.D.

Jerussi Consulting, Inc.