



June 24, 2004

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Pursuant to 21 CFR 10.20 and 10.30, the undersigned submits this petition under 21 CFR 333.310 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of the Food and Drug Administration to make a determination that its Drying Lotion™, a Topical Acne Drug Product for Over the Counter Human Use in 21 CFR 333 Subpart D can contain in combination both Sulfur (10.0%) and Salicylic Acid (2.0%) as the active ingredients.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that a Topical Acne Drug Product for Over the Counter Human Use that is covered under 21 CFR 333 Subpart D, can contain in combination both Sulfur (10.0%) and Salicylic Acid (2.0%) as the active ingredients. Pursuant to 21 CFR 333.310 (c) and (d) of the Federal Food, Drug and Cosmetic Act, the acne active ingredients are listed as Salicylic Acid from 0.5 to 2.0% and Sulfur from 3.0% to 10% respectively. However, under this provision, Salicylic Acid and Sulfur cannot be used at these levels in combination. The petitioner seeks a change in order to combine both Sulfur (10.0%) and Salicylic Acid (2.0%) as the active ingredients in its Drying Lotion™.

B. Statements of Grounds

Acne is a disease that involves the oil glands and hair follicles of the skin, which is manifested in the formation of blackheads, whiteheads, acne pimples, and acne blemishes. An acne drug product is a drug product that is used to reduce the number of blackheads, whiteheads, acne pimples, and acne blemishes. It is the reduction of *P. acnes* on the skin that brings about the treatment of acne manifested by the reduction of lesion count. Due to their antimicrobial properties, Sulfur and Salicylic Acid individually act to reduce the bacteria present in the skin. The panel reviewing the various acne treatments for 21 CFR 333 Subpart D, only considered ingredients that actually treated acne by a

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reduction of lesion counts (FR v56, #159, p41009). Both Sulfur and Salicylic Acid have shown to treat acne by a reduction in lesion count and are listed in the final monograph 21 CFR 333.310 as active ingredients for Topical Acne Drug Products.

For over 20 years, the petitioner, D'ARCY Laboratories, had produced the Drying Lotion™ acne treatment containing the active ingredients Sulfur (10%) and Salicylic Acid (2%) in the final product as sought for in this petition. Of the hundreds of thousands of bottles sold during this time, there have been no complaints, lawsuits or inquiries into injury associated with this formulation. In addition, there has been a less than 2% return rate for D'ARCY Laboratories' Drying Lotion™. The only negative comment indicated by consumers has been excessive dryness to the skin on the isolated blemish area as opposed to the whole face as found with other acne treatments. Finally, D'ARCY Laboratories has received thousands of customer testimonials praising the efficacy of the Drying Lotion™ acne treatment formulation sought for in this petition, and has attached a small sampling of these testimonials (See Testimonials annexed hereto as Attachment I).

After the FDA inspection of D'ARCY Laboratories on August 18-21, 2003, the petitioner reformulated its Drying Lotion™ acne treatment to conform with the current monograph 21 CFR 333.310. The current reformulated Drying Lotion™ contains Sulfur at 10.0% and has a Salicylic Acid content of 0.45%. Essex Testing Clinic, Inc. evaluated this formulation by a Repeat Insult Patch Test (RIPT). The testing concluded that this formulation of the Drying Lotion™ “was ‘Dermatologist-Tested’ and did not induce skin irritation or show any evidence of induced allergic contact dermatitis in human subjects” (See Report annexed hereto as Attachment II). The petitioner has also included a copy of the Drug Facts label for the Drying Lotion™ Overnight Acne Treatment (See Attachment III). The petitioner asserts that this reformulated version of the Drying Lotion™ lacks the efficacy of the original formulation in the overnight reduction of acne.

The petitioner has had the original formulation of the Drying Lotion™ sought for in this petition evaluated by Repeat Insult Patch Test (RIPT) by Essex Testing Clinic, Inc. The testing concluded that the original formulation of the Drying Lotion™ sought for in this petition “was ‘Dermatologist-Tested’ and did not induce skin irritation nor show any evidence of induced allergic contact dermatitis in human subjects” (See Report annexed hereto as Attachment IV).

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 CFR 25.31 as provided for in 21 CFR 25.30. Therefore, an environmental assessment is not required for the requested action.

D. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. The petitioner will promptly provide such information if so requested.

E. Certification

The undersigned certifies that, to its best 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,

Signed: 

Peter Gertas
Technical Director
D'ARCY Skincare

Attachments:

- I. Customer Testimonials
- II. Essex Testing Clinic Panel No.: 03282, Entry No.: 10231
- III. Copy of D'Arcy Laboratories Drying Lotion™ Drug Facts label
- IV. Essex Testing Clinic Panel No.: 04137, Entry No.: 10636