Lannett

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December 4, 2013

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

**SUITABILITY PETITION**

Dear Sir/Madam:

The undersigned submits this petition under Sections 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDCA, or the "Act") and 21 CFR § 314.93 to request that the Commissioner of Food and Drugs determine that Abbreviated New Drug Applications (ANDA) may be submitted for drug products that are not identical to the Reference Listed Drug (RLD) in active ingredient strength for Hydromorphone Hydrochloride Tablets and Oral Solution.

A. **Action Requested**

The petitioner seeks a determination from the Commissioner of Food and Drugs that ANDAs may be submitted for Hydromorphone Hydrochloride Tablets, 1 mg (scored tablets) and Hydromorphone Hydrochloride Oral Solution, 1 mg per 5 mL.

B. **Statement of Grounds**

Lannett Company, Inc. (Lannett) would like to file an ANDA for Hydromorphone Hydrochloride Tablets, 1 mg (scored tablets) and an ANDA for Hydromorphone Hydrochloride Oral Solution, 1 mg per 5 mL. Lannett currently has ANDAs approved for Hydromorphone Hydrochloride Tablets, 2 mg and 4 mg (ANDA 078439) and Hydromorphone Hydrochloride Tablets, 8 mg (ANDA 077471).

The RLD product, DILAUDID, is approved in 2 mg, 4 mg and 8 mg tablets and 1 mg/mL oral solution. Please refer to **Attachment 1** for a copy of the pertinent pages from the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) which lists the approved RLD products referenced in this petition.

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Lannett believes that the changes in strength for the proposed drug products do not pose questions of safety or effectiveness because the use, dose, and route of administration of the proposed drug products are the same as that of the listed drug products. The amount of drug substance in each proposed drug product does not exceed a previously approved amount of active ingredient.

Further, in the FDA-approved RLD package insert (please refer to **Attachment 2**), in the INDIVIDUALIZATION OF DOSAGE section, it states "elderly patients may require lower doses than the typically initiated oral dose of 2-4 mg every four hours." Additionally, in the Geriatric Dosage Handbook, 18th Edition, a highly respected, authoritative, peer-reviewed publication edited by a group of three university professors, it states that an oral dosage of 1-2 mg every 4-6 hours is appropriate for geriatric patients (please refer to **Attachment 3**). Based on these references, Lannett believes that there is a therapeutic benefit for the lower dosage strength.

The FDA-approved package insert for the RLD products, DILAUDID TABLETS AND DILAUDID ORAL LIQUID, is provided in **Attachment 2**. The proposed package insert for the Lannett products is provided in **Attachment 4**.

For all the reasons mentioned above, the Commissioner should approve this petition no later than 90 days after this petition is submitted and authorize the submission of an ANDA for the aforementioned strengths of Hydromorphone Hydrochloride Tablets ( 1 mg scored tablets) and Oral Solution (1 mg per 5 mL).

C. **Environmental Impact**

The actions requested herein are subject to categorical exclusion under 21 CFR §25.31(a).

D. **Economic Impact**

An economic impact statement will be submitted upon request should the Commissioner determine such assessment is necessary in evaluating this petition.

E. **Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, 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.

Please direct any questions or comments regarding this submission to my attention via phone at (215) 333-9000, ext. 2210, e-mail at apbedrosian@lannett.com or facsimile at (215) 624-2126.

Sincerely,

Arthur Bedrosian
President and CEO

Attachments:

Attachment 1: "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) excerpt
Attachment 2: RLD package insert for DIAUDID TABLETS AND DILAUDID ORAL LIQUID
Attachment 3: Excerpt from Geriatric Dosage Handbook, 18th Edition
Attachment 4: Proposed package insert

From: (215) 333-9000
Kristie Stephens
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Origin ID: IRCA

FedEx Express

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ActWgt: 2.5 LB
CAD: 101271069/INET3430

Delivery Address Bar Code

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**Food and Drug Administration**
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**Rockville, MD 20852**

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