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VIA FEDERAL EXPRESS

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

ANDA SUITABILITY PETITION

DLA Piper Rudnick Gray Cary US LLP submits this ANDA Suitability Petition under the provisions of section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93 requesting that the Commissioner of Food and Drugs allow the submission and filing of an Abbreviated New Drug Application (“ANDA”) for Amlodipine Besylate Capsules 2.5, 5, and 10 mg as discussed below.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs allow the submission and filing of an ANDA for Amlodipine Besylate Capsules 2.5, 5, and 10 mg pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93. Currently, Amlodipine Besylate is available as 2.5, 5, and 10 mg tablets from Pfizer and is sold under the brand name NORVASC®. The proposed change in dosage form from an immediate release tablet to an immediate release capsule is the type of change that has been expressly authorized in the statute and by FDA regulations. The Agency has approved many other ANDA Suitability Petitions requesting a similar type of change in dosage form. Labeling will be identical to NORVASC® except for those changes required due to different manufacturers and any labeling protected by patent or exclusivity. Further discussion is provided below.

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B. Statement of Grounds

1. As noted above, Amlodipine Besylate is available as 2.5, 5, and 10 mg tablets from Pfizer and sold under the brand name NORVASC®. NORVASC® Tablets approved by FDA under NDA 19-787 are designated as the reference listed drug (“RLD”) in the publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for the purpose of serving as the RLD for generic products.
2. The proposed product, Amlodipine Besylate Capsules are intended to meet the 90% confidence limits in terms of rate and extent of absorption when compared to the RLD in a comparative *in vivo* bioavailability study. In addition, an *in vitro* dissolution profile study will be conducted comparing the proposed product, Amlodipine Besylate Capsules to the RLD NORVASC®.
3. The proposed change in dosage form from an immediate release tablet to an immediate release capsule is the type of change that has been expressly authorized in the statute and by FDA regulation. In the past, the Agency has approved numerous ANDA Suitability Petitions for similar types of changes.
4. Pediatric studies have been conducted on Amlodipine Besylate and Pfizer has been granted 6 months of pediatric exclusivity for the patents for NORVASC® Tablets that are listed in FDA’s Orange Book.
5. Labeling will be identical to the RLD except for those changes required due to different manufacturers and any labeling protected by patent or exclusivity applicable to the RLD.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR § 25.31.

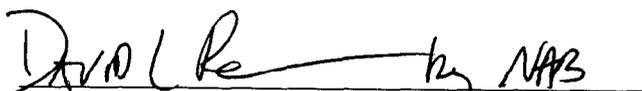
D. Economic Impact

By allowing the submission and filing of an ANDA for Amlodipine Besylate Capsules 2.5, 5, and 10 mg the public will be afforded access to an alternative dosage form for Amlodipine. Some patients may prefer to take a capsule as opposed to a tablet.

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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.

A handwritten signature in black ink, appearing to read "David Rosen" followed by a flourish and the initials "NAB". The signature is written over a horizontal line.

David Rosen, B.S. Pharm., J.D.
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