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# Vintage Pharmaceuticals

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November 14, 2008

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Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

## SUITABILITY PETITION

Pursuant to 21 CFR 10.20 and 10.30, Vintage Pharmaceuticals is submitting this petition under Section 505(j)(2)(C) of the Federal Food Drug and Cosmetic Act to request that the Commissioner of the Food and Drug Administration make a determination and declare that an Abbreviated New Drug Application (ANDA) is suitable for filing of Oxycodone Hydrochloride Capsules, 5 mg.

### A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration declare that Oxycodone Hydrochloride Capsules, 5 mg be determined suitable for submission under an ANDA. The marketed drug product upon which this petition is based is Oxycodone Hydrochloride Tablets USP, 5 mg approved under ANDA 77-290 (KV Pharmaceuticals).

### B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that has a different dosage form than the reference listed product provided that the FDA has approved a suitability petition proposing such an application.

Oxycodone Hydrochloride Tablets USP, 5 mg are marketed by KV Pharmaceuticals under ANDA 77-290 for oral administration as a narcotic analgesic for the treatment of moderate to severe pain. In support of this, a copy is provided of the applicable page from the FDA's electronic *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book (Attachment 1). The drug product proposed in this petition is Oxycodone Hydrochloride Capsules, 5 mg. Oxycodone has been marketed for many years as an orally administered single active ingredient in the tablet dosage form. Oxycodone has also been marketed in the oral capsule dosage form in combination with acetaminophen. Thus, an oral capsule dosage form containing oxycodone hydrochloride has already been approved by the Agency. The single active ingredient capsule drug product proposed in this petition would be bioequivalent to the RLD product - Oxycodone Hydrochloride Tablets USP, 5 mg.

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Oxycodone hydrochloride active drug substance and oxycodone hydrochloride single active ingredient tablets are currently listed in the USP, having official drug monographs (Attachment 2). The 5 mg tablet and 5 mg capsule products will have the same active ingredient, and will only differ in their dosage form, tablet versus capsule. Both drug products are immediate release oral dosage forms. Oxycodone hydrochloride after oral administration has high oral bioavailability when compared to other orally administered narcotic drug products. (Attachment 3).

The active ingredient, oxycodone hydrochloride, is a semi-synthetic narcotic with multiple actions qualitatively similar to those of morphine for the treatment of moderate to severe pain. The capsule will provide the prescribing physician with an alternate dosage form for those patients having difficulty swallowing tablets. In addition, the low strength capsule, like the tablet, will provide for individual low dose titration when needed to adjust treatment of moderate to severe pain symptoms.

The proposed drug product will meet the current bioequivalence requirements under Section 505(j)(2)(A)(iv) of the Act, and will have the same therapeutic effect as the listed drug products when administered for use as indicated in the approved product labeling. The labeling of the proposed drug product will be identical to the reference listed drug product with the exception of company name, product description and how supplied information. A package insert for the reference listed product is attached (Attachment 3).

Therefore, the petitioner requests that the Commissioner find that a change in dosage form of Oxycodone Hydrochloride Tablets, 5 mg to Oxycodone Hydrochloride Capsules, 5mg, with no change in route of administration, should raise no questions with regard to safety or efficacy and the FDA should approve this Suitability Petition.

#### **C. Pediatric Use Information**

We request a waiver from the Pediatric Research Equity Act of 2003 (PREA) for this new capsule dosage form of Oxycodone Hydrochloride 5 mg because it does not change the assessment of safety or effectiveness of the drug for the claimed indications. The drug product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients.

#### **D. Environmental Impact**

This action is categorically excluded from the requirement to submit an environmental assessment report under 21 CFR 25.31.

#### **E. Economic Impact**

The petitioner does not believe this is applicable, but will provide such an analysis if requested by the Agency.

**F. Certification**

The undersigned certifies that to the best of its knowledge and belief, this petition includes all the information and views upon which the petition relies, and that it includes representative data and information available to the petitioner which are unfavorable to the petition.

Sincerely,



Diane Servello,  
Sr. Director, Regulatory Affairs

- Attachments:
1. Page from Electronic Orange Book
  2. USP monographs for Drug Substance and Drug Product
  3. Package insert for marketed product

From: Origin ID: HSVA (256) 859-4011  
Kimberly Franklin  
Vintage Pharmaceuticals, LLC  
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Huntsville, AL 35811



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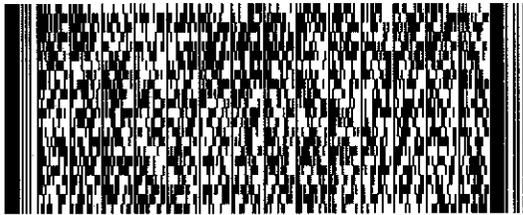


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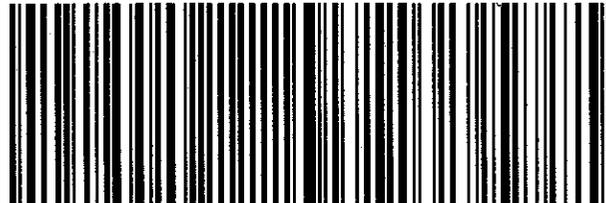
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