



July 16, 2020

RE: Storage Conditions for Dronabinol 2.5mg and 5mg Soft Gelatin Capsules CIII

To Whom it May Concern:

The labeled storage conditions for **AHP Dronabinol 2.5mg and 5mg Soft Gelatin Capsules 100 Unit Dose Blisters CIII** is 2° to 8°C (36° to 46°F). In addition, the product should be protected from freezing.

With regard to excursions beyond the labeled storage conditions; AHP has performed a 3-month room temperature stability study (25°C/60% RH) on AHP Dronabinol 2.5mg and 5mg Soft Gel Capsules 100 Unit Dose Blisters. During the 3-month study period, there was no significant chemical or physical degradation of the product. In addition, the manufacturer has indicated that they performed a 1 month open container study which also showed no significant degradation of the product. Therefore, study data does indicate that short-term storage in room temperature conditions will not impact the safety or efficacy of the product.

The intention of this letter is to provide information to help our hospital and pharmacy customers to develop internal procedures for the handling and storage of refrigerated products. American Health Packaging cannot advise the storage of AHP Dronabinol 2.5mg and 5mg Soft Gelatin Capsules 100 Unit Dose Blisters outside the FDA approved labeled storage conditions.

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2020 Dronabinol stability

Final Audit Report

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