ABBOTT

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Docket Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA 305, Room 1-23 Park Building
12420 Parklawn Drive
Rockville, MD 20857

RE: Citizen's Petition for ANDA Suitability for Midazolam Hydrochloride Injection, 5 mg (base)/mL, 10 mL ADD-Vantage® vial (Preservative Free)

The undersigned submits this petition under 21 CFR § 10.30 of the Federal Food, Drug, and Cosmetic Act 505 (b), 21 U.S.C. § 355 which authority has been delegated to the Commissioner of the Food and Drug Administration under 21 CFR § 5.10 and section 505(j)(2)(c) of the "Drug Price Competition and Patent Term Restoration Act of 1984".

Action Requested

The petitioner requests that the Commissioner permits an abbreviated new drug application (ANDA) to be filed for the Midazolam Hydrochloride Injection 5 mg/mL, 10 mL ADD-Vantage® vial (Preservative Free).

- The listed drug is Versed® (Midazolam Hydrochloride) 5 mg/mL vial, manufactured by Hoffman-LaRoche Inc. and is indicated for both intravenous (IV) and intramuscular (IM) routes of administration.
- The variation requested in this petition is to allow the use of the Midazolam Hydrochloride Injection 5 mg/mL, 10 mL ADD-Vantage® vial (Preservative Free) for the continuous intravenous route of administration only.

Statement of Grounds

The proposed Midazolam Hydrochloride Injection 5 mg/mL, 10 mL ADD-Vantage® vial (Preservative Free) is identical to the listed product in terms of active ingredient, dosage form, and strength. The only difference between the two products is that our proposed product will be limited for the continuous intravenous infusion route of administration. The safety and effectiveness of Midazolam Hydrochloride Injection has previously been demonstrated by the innovator for this route of administration.

01P-0136 CP1

The current practice in the Intensive Care Units consists of withdrawing the product from one or more conventional vials and adding it to the IV bag, and infusing using a standard pump and set. An ADD-Vantage® vial for Midazolam Hydrochloride 5 mg/mL will offer significant benefits over conventional vials:

1. ADD-Vantage® system will decrease product manipulations, reducing the risk of dosage errors and enhancing patient safety.
2. ADD-Vantage® is inherently a needleless system and therefore, minimizes the possibility of "needle sticks" for healthcare workers, in accordance with the Needlestick Safety and Prevention Act of 2000.
3. ADD-Vantage® system significantly reduces the time and labor cost required for mixing the drug product with diluent.
4. ADD-Vantage® system facilitates record keeping required for this schedule IV controlled substance.

The medical rationale for the proposed product in the 10 mL ADD-Vantage® vial is provided as Exhibit I.

A copy of the approved package insert for the innovator product, Versed® 5 mg/mL is provided as Exhibit II. The proposed insert for Midazolam Hydrochloride Injection 5 mg/mL, 10 mL ADD-Vantage® vial is provided as Exhibit III. We are also providing a side-by-side comparison of our proposed insert with the innovator's insert in Exhibit IV for the ease of review. We considered removing references to intramuscular administration from our package insert for the proposed product. However, it has been our experience that the Agency would like us to keep references to all modes of administration to match the innovator's labeling even if the product is approved for a specific route of administration. We propose to include the following statement on the first page of the insert to highlight the use of ADD-Vantage® vial for IV use only.

> *"The ADD-Vantage® vials are intended for intravenous administration as a single-dose injection only after dilution with ADD-Vantage® flexible diluent container."*

Environmental Impact

We hereby request a categorical exclusion under 21 CFR §25.24 (c) (1). The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than that for the listed product.

Economic Impact

This information will be submitted if requested by the Commissioner.

Certification

We include in Exhibit V a signed Certification Statement as required by 21 CFR 10.30.

We trust that the information presented in this Suitability Petition is complete and shows our proposed product to be suitable for an abbreviated new drug application.

Sincerely,

ABBOTT LABORATORIES

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Table of Contents