

Food and Drug Administration
Rockville MD 20857

1998 08 05 - 1 P 07

AUG - 5 2002

Abbott Laboratories
Attention: Surendera K. Tyagi
D-389 Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-6157

Docket No. 01P-0136/CP1

Dear Mr. Tyagi:

This is in response to your petition filed on March 20, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Midazolam Hydrochloride Injection, 5 mg(base)/mL, 10 mL vials (ADD-Vantage® vials). The listed drug product to which you refer in your petition is Versed® (Midazolam Hydrochloride) Injection, 5 mg (base)/mL, 1 mL, 2 mL, 5 mL, and 10 mL vials, approved under NDA 18-654, held by Hoffman La Roche, Inc.

Your request involves a change in the route of administration. The listed drug, Versed® (Midazolam Hydrochloride) Injection, is approved for the intravenous (IV) and intramuscular (IM) routes of administration. You are requesting permission to submit an ANDA for the continuous intravenous route of administration only. Therefore, you are deleting certain routes of administration from the labeling. The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

In addition, this petition and your waiver request were evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The FDA has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in the pediatric population, because this specific drug product is adequately labeled for pediatric use.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a route of administration that differs from the route of administration of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing route of administration.

01P-0136

PAV1

01P-0136/CP1
Abbott Laboratories

The FDA finds that the change in the route of administration for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product have been previously approved for the listed drug product. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

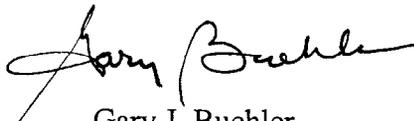
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research