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November 27, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Citizen Petition

The undersigned submits this petition under Section 505 (j) (2) (c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of Food and Drugs to declare the Diazepam Injection (DiaJect™) Auto-injector as suitable for consideration in an abbreviated new drug application.

A Diazepam Auto-injector is approved under NDA 20-124. The Army is the holder of this NDA. This Diazepam Auto-injector is made for the Army by Meridian Medical Technologies (MMT). Diazepam contained in the Auto-injector is delivered intramuscularly in a 2 mL dose that contains 10 mg of Diazepam. The drug concentration and dose (5 mg/mL of Diazepam) for the DiaJect Auto-injector will be the same as the drug concentration and dose in the Army's Diazepam Auto-injector.

Although it has never been a discontinued product, the Army's Diazepam is on the discontinued drug product list in the Orange Guide. The Diazepam Auto-injector is currently being manufactured and sold to the Army by Meridian Medical Technologies (MMT). Although we are not certain of the reason that an active product is on the discontinued list we know there are no safety or efficacy issues with this product. MMT is submitting this petition in order use the Army's Diazepam Auto-injector product as the reference listed drug (RLD) in our ANDA application.

The active drug ingredient, strength, indications, route of administration, container closure system and total drug contents of the Army's Diazepam are identical to those of the proposed DiaJect Auto-injector product. The safety and effectiveness of Diazepam IM injection has previously been established by the innovator indicating MMT's proposed drug has the same safety and efficacy. There is no known data to the petitioner to indicate that the Army's Diazepam Auto-injector is not a safe product when used as directed in the Diazepam Auto-injector Dosage section of the Army package insert found in Attachment 1. A copy of the proposed package insert for the DiaJect Auto-injector is enclosed in

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Attachment 2. The proposed product, DiaJect Auto-injector, and the product MMT proposes to use as the reference listed drug product (Army's Diazepam Auto-injector) are compared in **Table 1**.

Table 1

Product	Route of Administration	Dosage Form	Concentration	Dose
(existing) Diazepam Auto-injector	Intramuscular	Solution	5 mg/mL Diazepam	2 mL
(proposed) DiaJect Auto-injector	Intramuscular	Solution	5 mg/mL Diazepam	2 mL

The proposed ANDA product would provide a "ready to use" dosage form of Diazepam contained in an Auto-injector that is currently not available on the commercial market.

Respectfully,



Thomas Freund
Manager, Regulatory Affairs

Action Requested

This petition seeks a determination that the Army's Diazepam Auto-injector product is safe and effective. The petitioner is seeking this request in order to use the Army's Diazepam Auto-injector product as the reference listed drug in the ANDA application for the proposed MMT Auto-injector product containing Diazepam, DiaJect.

Statement of Grounds

The Army's Diazepam Auto-injector has been approved since 1990 by the FDA (NDA 20-124) and is a safe and effective drug. The product was never listed in the approved drug section of the Orange Guide. MMT is the sole supplier of this product used by the Army. Container closure components, drug substance, drug formulation, drug filling equipment and raw materials used in the manufacturing of the Army's Diazepam Auto-injector will be the same materials used by MMT in the manufacturing of the DiaJect Auto-injector product. The rationale for developing such a product is that the product would offer the benefits of the IM delivery of Diazepam in an Auto-injector that is currently not commercially available.

Environmental Impact

An environmental impact analysis report for the action requested (the determination that Diazepam (DiaJect) Auto-injector, 5 mg/mL in 2 mL, is suitable for ANDA) is not required as cited under 21CFR 25.31 (a).

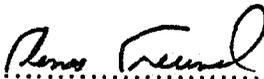
Economic Impact

Not applicable

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 know to the petitioner which are unfavorable to the petition.

Signature


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Name of Petitioner

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Contact Person:

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Manager, Regulatory Affairs