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December 11, 2003

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

Re: Dihydroergotamine Mesylate Injection, 2 mg/ml

ANDA SUITABILITY PETITION

The undersigned submits this Suitability Petition (the "Petition") under the provisions of the Federal Food, Drug and Cosmetic Act, Section 505(j)(2)(C) and 21 C.F.R. § 314.93 to request the Commissioner of Food and Drugs to allow submission of an abbreviated new drug application (ANDA) for dihydroergotamine mesylate injection 2 mg/ml, in a single dose, pre-filled syringe.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs declare that dihydroergotamine mesylate injection 2 mg/ml in a single dose, 0.5 ml pre-filled syringe is suitable for submission in an ANDA. The reference listed drug (RLD) upon which this Petition is based is D.H.E. 45® (dihydroergotamine mesylate) Injection 1mg/ml, which is available in one presentation as a glass ampoule containing 1 ml. of solution for use as a

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single dose. D.H.E. 45 is indicated for use in adults in the acute treatment of migraine headaches with or without aura.

B. Statement of Grounds

The reference listed drug product, D.H.E. 45 Injection, is packaged as an ampoule containing 1 mg. of the active ingredient, dihyrdroergotamine mesylate, in 1 ml. of solution. The proposed drug product will be packaged as a single use, pre-filled syringe containing 1 mg. of the same active ingredient, dihydroergotamine mesylate, in 0.5 ml. of solution. Like D.H.E. 45 Injection, the proposed product will contain a total drug content of 1 mg. It will, therefore, provide the same amount of drug as a single dose of D.H.E. 45 Injection, but with a reduced volume of injection. The reduction in volume will provide a more comfortable administration of drug by reducing duration of needle stick and will minimize backflow during subcutaneous administration. The proposed product will also provide the convenience of a pre-filled syringe, and thereby provide for greater simplicity of use and reduce the time required to prepare the product for administration, useful features in a product intended for use by migraine patients.

Copies of labeling of the RLD upon which this Petition is based and draft labeling for the proposed product are attached as Attachments 1 and 2, respectively. The proposed labeling is the same as that of the RLD with the exception of changes because the manufacturer is different and changes in the How Supplied section [and in the Instructions for Use] which relate to the presentation of the proposed product in a pre-filled syringe. There are no changes, however, in the indications, uses or warnings from that of the RLD. In short, the uses, dose and route of administration of the proposed drug product are the same as that of the listed drug product.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petitioner relies and that it includes representative data and information known to the Petitioner, which are unfavorable to the Petition.

We trust you will find the information in the Petition to be satisfactory for your review and approval. If there are any questions or you require further clarification, please do not hesitate to contact me at 919-313-4750. I can also be contacted by fax at 919-313-4751.

Respectfully submitted,

Marc H. Shapiro (by SMB)

Marc H. Shapiro