



Pharmaceutical Resources Group

1070 5 107-1110

1 February 2005

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

Enclosed please find a citizen petition requesting permission to submit an Abbreviated New Drug Application (ANDA) for a proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**. The petition contains Package Insert attachments for both the RLD (Attachment 1) and the proposed drug (Attachment 2). Changes in the proposed drug insert from the RLD are shown by highlight.

Please contact the undersigned if there are questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Michael J. Walters'.

Michael J. Walters
President
PRG Consulting
312 Broad Armstrong Drive
Brownsboro, AL 35741
256-509-4190

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Pharmaceutical Resources Group

Suitability Petition

In compliance with Section 505(j)(2)(C) of the Federal Food Drug and Cosmetic Act, the undersigned is requesting permission from the Commissioner of the Food and Drug Administration to file an Abbreviated New Drug Application (ANDA) for the drug product, **Colistimethate Sodium 150 mg/2 mL Solution**. The sole difference between this proposed new product and the reference listed drug is form. The new product is to be marketed as a sterile, preservative-free solution instead of a lyophilized product that requires reconstitution with WFI prior to use.

A. Action Requested

To seek a determination by the Commissioner of the Food and Drug Administration that the drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, is suitable for submission as an abbreviated new drug application (ANDA). The pertinent referenced listed drug (RLD) for this product, COLY-MYCIN M PARENTERAL (Monarch Pharmaceuticals Inc.), was approved on June 4, 1970 (NDA No. 50-108).

Further, in this petition, the undersigned requests a waiver from the requirement to conduct pediatric studies based on the pre-existence of such studies as indicated by the well-defined dosage information for pediatric and adult populations contained in the RLD labeling. (Attachment 2)

B. Statement of Grounds

- Concentration is in accordance with the reconstituted RLD

The concentration of the proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, will be the same as the concentration produced when following the instructions found in the package insert for the RLD COLY-MYCIN M PARENTERAL (Monarch Pharmaceuticals Inc.), a lyophilized product.

- Proposed product is equivalent in use, dosage, and administration.

The intended use of the proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, will be the same as approved for the RLD. The dosage and route of administration will be identical to that for the reconstituted RLD product.

- Proposed drug will have the same therapeutic effect.

The proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, is expected to have the same therapeutic effect as the RLD because the dosage and route of administration are the same as the RLD (when it is reconstituted). The diluent, sterile water, proposed for use in the manufacturing of the proposed new drug is the same diluent recommended for use in reconstitution of the RLD.

- Proposed new drug product eliminates need for reconstitution and may therefore reduce the possibility of dilution errors or microbial contamination during reconstitution.

The major advantage of the proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, will be convenience of use. The proposed new drug product eliminates the need for reconstitution, thus preventing the possibility of dilution errors. Additionally, there is less opportunity to contaminate the product through handling of the diluent during the reconstitution of the lyophilized material.

By eliminating the reconstitution step, the proposed new drug product may offer a more convenient dosage option.

The package insert for the RLD, a lyophilized product, COLY-MYCIN M PARENTERAL (Monarch Pharmaceuticals Inc.) is provided in Attachment 1 of this petition. The draft package insert for the proposed **Colistimethate Sodium 150 mg/2 mL Solution** product is provided in Attachment 2.

In summary, the proposed new drug product, **Colistimethate Sodium 150 mg/2 mL Solution**, will provide a convenient sterile solution equivalent to the approved RLD product when reconstituted. Since the proposed new drug product is formulated to contain the same concentration of the same active ingredient, colistin base; (150 mg/ 2ml) as the RLD, the proposed new drug product can be expected to have the same therapeutic effect as the RDL when administered to patients for the conditions listed in the labeling of he RLD product.

C. Pediatric Use Information

The petitioner requests a waiver from the regulations cited in 21CFR314.55 requiring one to conduct clinical studies in pediatric patients for the following reasons:

- Pediatric studies have been conducted and are referenced in the current package insert for the RLD.
- Pediatric dosing regimens are included with the adult dosage information found in the package insert for the RLD.

D. Environmental Impact

The petitioner requests a waiver from this requirement of an environmental assessment or impact statement under 21CFR25.31 (a).

Economic Impact

The petitioner will provide the information upon request by the Commissioner of the Food and Drug Administration.

F. Certification

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

Sincerely yours,



Michael J. Walters
President
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