CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-260

SUMMARY REVIEW

DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Divisional Memorandum

NDA: 22-260 (epoprostenol IV)

Sponsor: GeneraMedix

Review date: 21 June 2008

Reviewer: N. Stockbridge, M.D., Ph.D., HFD-110

Distribution: NDA 22-260
DCaRP/Fortney

This is a new generic formulation of epoprostenol for intravenous use, differing from Flolan by substitution of arginine [redacted] instead of Flolan's glycine, but this difference suffices to have the NDA reviewed in OND rather than OGD. b(4)

There are no CMC issues (McLamore; 10 June 2008), no microbiology issues (Lolas; 28 January 2008, 8 May 2008). There are no pharmacology/toxicology, carcinogenicity, clinical pharmacology, or statistical reviews.

There are no clinical studies. The medical review (Williams; 11 May 2008) recommended withholding approval pending a study to assess the potential for phlebitis, a theoretical concern arising because the reconstituted drug has a pH >11. This issue was discussed internally and with the sponsor. I concluded that this was not a valid concern based on the very low infusion rate, even compared with blood flow in a peripheral vein (100-fold larger than infusion rate), and much less for the usual use in a central vein.

I conclude that this application should be approved.

APPEARS THIS WAY ON ORIGINAL

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/s/

Norman Stockbridge
6/21/2008 11:06:06 AM
MEDICAL OFFICER