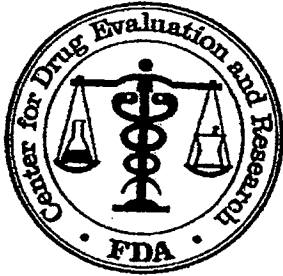


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-276

SUMMARY REVIEW



DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Divisional Memorandum

NDA: 22-276 (nicardipine IV)
Sponsor: Teva Parenteral Medicines
Review date: 16 June 2008

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

Distribution: NDA 22-276
DCaRP/Crowley

This is a new generic formulation of nicardipine for intravenous use, differing from Cardene IV by substitution of benzoic acid instead of Cardene's citric acid, but this difference suffices to have the NDA reviewed in OND rather than OGD.

b(4)

There are CMC reviews by Dr. Soldatova (6 May and 4 June 2008), recommending approval with a 9-month expiry, and a pharmacology review of labeling by Dr. Resnick (31 March 2008) recommending minor changes to both the innovator and Teva labels. Since this is, for practical purposes, a generic product, the changes should be first applied to the innovator product.

I concur that this application should be approved.

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/s/

Norman Stockbridge
6/16/2008 12:13:48 PM
MEDICAL OFFICER