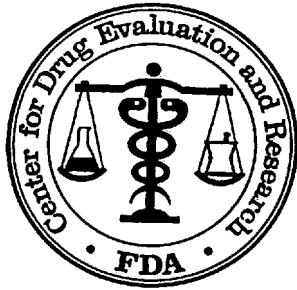


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

215252Orig1s000

SUMMARY REVIEW



DIVISION OF CARDIOLOGY AND NEPHROLOGY
Divisional Memorandum

NDA: 215252 (diltiazem hydrochloride injection)

Sponsor: Excela

Reviewer: N. Stockbridge, M.D., Ph.D.

The product is diltiazem 1 mg/mL in 125- and 250-mL bags. This is a 505(b)2 application relying upon the Agency's findings for Cardizem.

The OPQ review (Zhang/Kasi/Metcalf/Moony/Marasa/Adams/Carver) recommends approval. Facilities were cleared based on history. Expiry is set at 24 months based on 24 months stability testing. Although this is a combination product, there is no CDRH review.

The pharmacology/toxicology review (Datla) reports no issues with extractables and leachables.

Labeling has also been reviewed by DMEPA (Straka), OPDP (Newcomer), and DPMH (Mastroyannis). Their recommendations have been considered in the Division's review. At this writing there are minor labeling issues to be reconciled with the sponsor. If resolved, NDA 215252 will be approved.

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/s/

NORMAN L STOCKBRIDGE
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