

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-536

SUMMARY REVIEW



DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Divisional Memo

NDA: 22-536 Indomethacin for Injection IV (indomethacin for patent ductus arteriosus)

Sponsor: APP Pharmaceuticals

Review date: 17 March 2010

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

Distribution: NDA 22-536
HFD-110/Fortney

This memo conveys the Division's recommendation to approve Indomethacin for Injection, for patent ductus arteriosus.

This application has been the subject of reviews of CMC (Wong 18 February 2010) and microbiology (McVey 18 February 2010) only.

Previously approved formulations of intravenous indomethacin for this use are salts of sodium or lysine. This formulation is a free base in a buffered solution. The buffer makes this a 505(b)2 application.

There are no outstanding review issues. Labeling has content similar to existing formulations, but has been migrated to PLR format.

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22536

ORIG-1

APP
PHARMACEUTICA
LS LLC

INDOMETHACIN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE

03/17/2010