

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208424Orig1s000

MEDICAL REVIEW(S)



DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS

Divisional Memo

NDA: 208424 Nitroglycerin (GoNitro) to prevent and treat episodes of angina pectoris.

Sponsor: G. Pohl-Boskamp

Review date: 4 June 2016

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

This memo conveys the Division's recommendation to approve this application.

This application has been the subject of reviews of CMC (Sapru; 23 May 2016), pharmacology/toxicology (Gatti; 21 December 2015), and clinical pharmacology (Pillai; 1 June 2016). There is also a CDTL memo (Madabushi; 3 June 2016), with which I am in complete agreement.

This is a 505(b)(1) application relying upon safety and effectiveness of NitroLingual Pumpspray. There are no remaining product quality issues; the 400-mcg packets have an expiry date of 18 months. The facility inspections are complete.

There are no new nonclinical studies. The only clinical study assessed pharmacokinetics of parent and major metabolites in comparison with NitroLingual Pumpspray. That study demonstrates about twice the C_{max} and about 60% higher AUC of the parent for GoNitro delivered at the same nominal dose. This difference in exposure is not considered to be a problem; dosing is always adjusted by symptoms.

Nor does it appear that anyone is troubled by the whimsical product name.

Labeling negotiations are complete.

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/s/

NORMAN L STOCKBRIDGE
06/04/2016