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APPLICATION NUMBER:
202231Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
Application Number(s) 202,231
Priority or Standard Standard

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Division / Office DMEP/OND II

Reviewer Name(s) Naomi Lowy, MD
Review Completion Date May 11, 2011

Established Name Levothyroxine sodium for injection
(Proposed) Trade Name Levothyroxine sodium for injection
Therapeutic Class Thyroid hormone
Applicant APP Pharmaceuticals, LLC

Formulation(s) Injection
Dosing Regimen Initial loading dose of 300-500 µg IV followed by daily maintenance doses of 50-100 mcg until oral therapy is tolerated

Indication(s) Treatment of myxedema coma
Intended Population(s) Adults

Template Version: March 6, 2009

APPEARS THIS WAY ON ORIGINAL

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