

Exhibit 1009

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RESEARCH**

APPLICATION NUMBER:
202788Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA
Application Number(s) 202-788
Priority or Standard Standard

Submit Date(s) 04 March 2011
Received Date(s) 04 March 2011
PDUFA Goal Date 04 January 2012
Division / Office DAAAP/ODE2

Reviewer Name(s) Luke Yip, MD
Review Completion Date 15 December 2011

Established Name Fentanyl sublingual spray
(Proposed) Trade Name
Therapeutic Class Opioid analgesic
Applicant Insys Therapeutics, Inc

Formulation(s) Sublingual spray solution
Dosing Regimen PRN, not to exceed 4 doses
per 24 hours and not more
frequent than 4 hours apart
Indication(s) Breakthrough cancer pain
Intended Population(s) Adult cancer patients receiving
around the clock opioids with
breakthrough pain

Template Version: March 6, 2009

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