# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**202788Orig1s000**

# MEDICAL REVIEW(S)

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# 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 |

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Template Version:  March 6, 2009

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