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APPLICATION NUMBER:
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PHARMACOLOGY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number: NDA 202788
Supporting document/s: EDR Original Serial 000
Applicant's letter date: 3/4/11
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Product: Fentanyl Sublingual Spray
Indication: Management of breakthrough cancer pain in patients [REDACTED] (b) (4) [REDACTED] who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
Applicant: Insys Therapeutics, Inc.
Review Division: Division of Anesthesia, Analgesia and Addiction Products (DAAAP)
Reviewer: Elizabeth A. Bolan, Ph.D.
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