Office of Clinical Pharmacology Review

NDA or BLA Number	217470
Link to EDR	\\CDSESUB1\evsprod\NDA217470\0004
Submission Date	11/22/2022 Clinical Data Submission in this Rolling NDA.
Submission Type	[Priority review]
Brand Name	Opvee
Generic Name	Nalmefene HCl Nasal Spray
Dosage Form and Strength	2.7 mg nalmefene nasal Spray
Route of Administration	Intranasal route
Proposed Indication	Reversal of known of suspected opioid overdose-induced respiratory and CNS depression.
Applicant	Opiant Pharmaceuticals, Inc. a wholly-owned subsidiary of Indivior Inc.
Associated IND	[IND 136851]
OCP Division:	Division of Neuropsychiatric Pharmacology
OND Division:	Division of Anesthesiology, Addiction Medicine and Pain Medicine
Clinical Pharmacology Reviewer	Srikanth C. Nallani, Ph.D.
Clinical Pharmacology Team Leader	Yun Xu, Ph.D.
Pharmacometrics Reviewer	Michael Bewernitz, Ph.D.
Pharmacometrics Team Leader	Atul V. Bhattaram, Ph.D.
Division of Applied Regulatory Science (DARS) Reviewer	Zhihua Li, Ph.D.
DARS Team Leader	Jeffry Florian, Ph.D.

This is an addendum to the clinical pharmacology review in DARRTS dated 5/8/2023, with an update on the OSIS inspection result. The purpose of this addendum is to indicate that the Office of Study Integrity and Surveillance (OSIS) determined that an inspection is not needed for the site. Please refer to OSIS memo indicating acceptability of clinical site inspection (dated 5/10/2023).

Therefore, the clinical pharmacology review dated 5/8/2023 and the recommendation stands. The NDA 217470 for Opvee nalmefene nasal spray is acceptable from a clinical pharmacology perspective provided that the labeling revisions are accepted by the applicant.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SRIKANTH C NALLANI
05/12/2023 03:32:20 PM

YUN XU
05/12/2023 03:37:22 PM