## CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:** 

213436Orig1s000

**NON-CLINICAL REVIEW(S)** 

## **MEMORANDUM**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Food and Drug Administration

## Division of Pharmacology/Toxicology-Neuroscience (DPT-N) Center for Drug Evaluation and Research

Date: September 3, 2021 From: Edmund Nesti, PhD

Reviewer

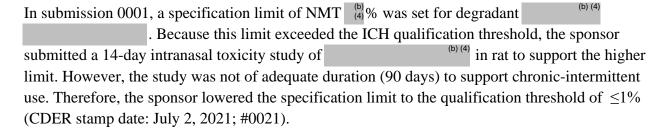
Subject: NDA 213436

Re: Submission 0001 (November 6, 2020) Product: Trudhesa (dihydroergotamine mesylate)

Indication: Acute treatment of migraine with or without aura

Applicant: Impel NeuroPharma, Incorporated

Trudhesa is a drug-device combination product developed for intranasal administration of dihydroergotamine (DHE) mesylate for the acute treatment of migraine with or without aura. The therapeutic activity is generally attributed to the agonist effects at the 5-HT $_{1D}$ . This NDA is a 505(b)(2) application referencing DHE 45 $^{\circ}$  injection (NDA 05929) and Migranal $^{\circ}$  Nasal Spray (NDA 20148). The maximum recommended daily dose is 2.9 mg.



Therefore, there is no objection to approval of the NDA from a nonclinical standpoint.

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/s/

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