FDA CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY
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Addendum

DATE	July 21, 2025
NDA	211759 Resubmission for Vyscoxa (celecoxib) oral suspension 10 mg/mL
SUBJECT	Update on OSIS Inspection Assessment
CLIN PHARM REVIEWER	Wei Qiu, Ph.D., Clinical Pharmacology Reviewer
CLIN PHARM TEAM LEADER	Deep Kwatra, Ph.D., Clinical Pharmacology Team Leader

The Office of Clinical Pharmacology/Division of Neuropsychiatric Pharmacology (OCP/DNP) has reviewed the information submitted in NDA 211759 resubmission for Vyscoxa (celecoxib) oral suspension 10 mg/mL, submitted on 9/30/2024. The clinical pharmacology review was finalized in DARRTS on 6/24/2025. It is stated in the review that from clinical pharmacology perspective, the information submitted in the NDA resubmission was acceptable (though significant labeling changes are needed) pending OSIS inspection and assessment on the comparative bioavailability study 915/22.

As stated in the clinical pharmacology review, per OSIS memo in DARRTS dated 1/31/2025, OSIS inspected the analytical portion of Study 915/22 conducted at (b) (4) (b) (4) OSIS concluded that there was no concern with the reliability of analytical data generated from Study 915/22. Based on the OSIS review in DARRTS dated 7/18/2025, OSIS arranged a clinical inspection of study 915/22 conducted at Quinta-Analytica, Prague, Czech Republic, there are no concerns regarding the reliability of the data or human subject protection for inspected study 915/22.

Therefore, from a clinical pharmacology perspective, the information submitted in the NDA 211759 resubmission is acceptable.

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/

WEI QIU
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DEEP KWATRA
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