U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

Statistical Review and Evaluation
Clinical Studies - NAI

NDA/BLA Serial Number:	NDA 205-383 Sequence 18
Drug Name:	Iohexol Powder for Oral Solution (Oraltag)
Indication(s):	Oraltag is an iodinated contrast agent indicated for **oral** use in adults and children for opacification of the gastrointestinal tract during computed tomography of the abdomen and pelvis.
Applicant:	Interpharma Praha, a.s. (US agent: Otsuka Pharmaceutical Development & Commercialization)
Date(s):	NDA re-submission: September 26, 2014 PDUFA Date:, July 25, 2015
Review Priority:	Standard
Biometrics Division:	
Statistical Reviewer:	Satish C. Misra, Ph. D.
Concurring Reviewers:	Jyoti Zalkikar, Ph. D., Team Leader Thomas Gwise, Ph. D., Deputy Division Director
Medical Division:	Division of Medical Imaging Products (DMIP)
Clinical Team:	Clinical: Harris E. Orzach, M.D. Clinical TL: Alex Gorovets, M. D.
Project Manager:	Thuy M Nguyen

EXECUTIVE SUMMARY

OralTag is an iodine-based oral contrast agent, which is used to opacify the gastrointestinal tract, for abdominal and pelvic CT scanning. The drug, contains the same active ingredient as prepared solutions of Omnipaque 300 (iohexol), which is the reference listed drug (RLD) for oral use.

NDA 205-383 was submitted to FDA on behalf of Interpharma Praha, a.s., by the US agent, Otsuka Pharmaceutical Development & Commercialization, Inc. on March 11, 2013 (Sequence 00). The clinical reviewer, Barbara Stinson recommended approval from the clinical perspective of the 505(b)(2) NDA for the product, which at that time was called (b) (4). This was based on the FDA's previous finding of safety and effectiveness of Omnipaque, which was approved under NDAs 18-956 and 20-608 and literature search. However, this NDA was not approved due to lack of meeting the CMC regulatory requirement and other deficiencies.

The sponsor resubmitted a complete response to all deficiencies outlined in the Complete Response letter of January 8, 2014, consistent with the proposal that was deemed acceptable by FDA on August 8, 2014 and this NDA was resubmitted on September 26, 2014. The CMC issues have been addressed in this submission.

Any new clinical/efficacy data were not required and were not submitted. Therefore, it is NAI from statistical perspective.

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/s/

SATISH C MISRA
03/02/2015

JYOTI ZALKIKAR
03/02/2015
I concur with the primary reviewer.

THOMAS E GWISE
03/02/2015