

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206910Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

MEMORANDUM



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

DATE: 31 July 2014

TO: NDA 206910

FROM: Bryan S. Riley, Ph.D.
Team Leader (Acting)
OPS/New Drug Microbiology Staff

THROUGH: John W. Metcalfe, Ph.D.
Senior Review Microbiologist
OPS/New Drug Microbiology Staff

cc: Linhua Tzeng, BSN, MS
LCDR, U.S. Public Health Service
Regulatory Project Manager
OND/DHP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for JADENU (deferasirox) 90 mg, 180 mg and 360 mg Film Coated Tablets [Submission Date: 30 May 2014]

The NDA for JADENU does not include a Microbial Limits specification for drug product release or stability; however, the applicant provides a suitable rationale for the exclusion of this testing. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

JADENU is a Film Coated Tablet for oral administration.

The applicant has proposed to not perform microbial limits testing on the drug product at release or on stability. Section 3.2.P.5.6 (Justification of Specifications) contained a risk assessment related to microbial control of the drug product (“Rationale for no microbial enumeration tests in release testing of ICL670 90 mg, 180 mg and 360 mg film-coated tablet”). The following points were considered when assessing the microbiological risk for the drug product:

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- (b) (4)

MEMORANDUM

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(b) (4)

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is suitably controlled.

END

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/s/

BRYAN S RILEY
08/01/2014

JOHN W METCALFE
08/01/2014
I concur.