CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208216Orig1s000

SUMMARY REVIEW

Summary Review for Regulatory Action

Date	(electronic stamp)
From	Ann. T. Farrell, M.D., Division Director
Subject	Division Director Summary Review
NDA/BLA # **Supplement #**	208216
Applicant Name	Actavis LLC
Date of Submission	June 30, 2015
PDUFA Goal Date	April 30, 2016
Proprietary Name / **Established (USAN) Name**	/azacitidine
Dosage Forms / Strength	Lyophilized powder in 100 mg vials
Proposed Indication(s)	Same indications as Vidaza
Action/Recommended Action:	**Approval – see label for final wording of indication**

Material Reviewed/Consulted OND Action Package, including:	
Medical Officer Review	George Shashaty, M.D./ Kathy Robie-Suh, M.D., Ph.D.
Regulatory Health Project Manager	Tracy Cutler
Statistical Review	N/A
Pharmacology Toxicology Review	Ramadevi Gudi, Ph.D./Christopher Sheth, Ph.D.
CMC Review/OBP Review	Laura Pogue, Ph.D./Anjanette Smith/David Keire, Ph.D./Haripada Sarker, Ph.D./Amit Mitra, Ph.D./David Anderson, Ph.D./Frank Wackes/Banu Zolnik, Ph.D./Okpo Eradiri/Rabiya Laiq/Anamitro Banerjee, Ph.D.
Microbiology Review	Nutan Mytle, Ph.D.
Clinical Pharmacology Review	N/A
DDMAC/OPDP/	Wendy Lubarsky/Ebony Ayres, PharmD/Yelena Maslov, PharmD
OSI	N/A
CDTL Review	Anamitro Banerjee, Ph.D.
OSE	N/A
Other -DPMH	Leyla Sahin, M.D./Tamara Johnson, M.D., M.S./Lynne Yao, M.D.

Signatory Authority Review Template

1. Introduction

This application for NDA 208216 is a 505 b2 application for azacitidine and seeks the same indications as Vidaza NDA #050794, the RLD.

2. Background

See introduction.

3. CMC/Device

No issue which would preclude approval was identified. The stability data support a 24 month shelf life.

4. Nonclinical Pharmacology/Toxicology

No issues that would preclude approval were identified. The labeling was revised to incorporate PLLR.

5. Clinical Pharmacology/Biopharmaceutics

No issues that would preclude approval were identified.

6. Microbiology

N/A

7. Clinical/Statistical-Efficacy

No clinical data was submitted.

8. Safety

No clinical data was submitted.

9. Advisory Committee Meeting

N/A

10. Pediatrics

The Applicant requested a waiver which was granted.

11. Other Relevant Regulatory Issues

None

12. Labeling

All disciplines made recommendations for labeling. DMEPA proposed carton and container revisions which were accepted by the Applicant.

13. Decision/Action/Risk Benefit Assessment

- Recommended regulatory action

Approval

- Risk Benefit Assessment

This application is a 505 b2 application for Vidaza.

- Recommendation for Post marketing Risk Management Activities
  None

- Recommendation for other Post marketing Study Requirements/ Commitments
  None

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/s/

ANN T FARRELL
04/15/2016