CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214120Orig1s000

PRODUCT QUALITY REVIEW(S)

Recommendation: APPROVAL

NDA 214120
Review #1

Drug Name/Dosage Form	Azacitidine Tablets
Strength	200 mg and 300 mg
Route of Administration	Oral
Rx/OTC Dispensed	R_x
Applicant	Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb
US agent, if applicable	n/a

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED
Original Submission	03-Mar-2020	All
Amendment (SD)	15-May-2020	DP
Amendment (SD)	21-May-2020	Process/facilities
Amendment (SD)	28-May-2020	DP, Biopharm, Process/facilities
Amendment (SD)	22-Jun-2020	DP, Biopharm
Amendment (SD)	08-Jul-2020	DP
Amendment (SD)	06-Jul-2020	Process/facilities
Amendment (SD)	16-Jul-2020	DP
Amendment (SD)	06-Sept-19	Process/Facilities

Quality Review Team

DISCIPLINE	PRIMARY REVIEWER	SECONDARY REVIEWER
Drug Master File/Drug Substance	Karina Zuck	Haripada Sarker
Drug Product	Nina Ni	Anamitro Banerjee
Process and Facilities	Huiquan Wu	Bogdan Kurtyka
Microbiology	n/a	n/a
Biopharmaceutics	Min Kang	Om Anand
Regulatory Business Process Manager	Rabiya Haider	n/a
Application Technical Lead	Sherita McLamore	n/a
Laboratory (OTR)	n/a	n/a

Environmental	Raanan Bloom	n/a

Quality Review Data Sheet

1. RELATED/SUPPORTING DOCUMENTS

A. DMFs:

DMF #	Type	Holder	Item Referenced	Status	Date Review Completed	Comments
(b) (4)	Type III		(b) (4)	n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA
	Type III			n/a	No Review	Adequate information provided in the NDA

B. Other Documents: *IND, RLD, or sister applications*

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	(b) (4)	Development of (b) (4)

2. **CONSULTS**
N/A

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