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RESEARCH**

*APPLICATION NUMBER:*

**209604Orig1s000**

**OFFICER/EMPLOYEE LIST**

Officer/Employee List  
Application: NDA 209604

The following officers or employees of the FDA participated in the decision to approve this application and consented to be identified on this list:

Deputy Director	Joseph Gootenberg
Clinical Team Leader	Gideon Blumenthal/ Erin Larkins
Clinical Reviewers	Lee Pai-Scherf
Regulatory Project Manager	Anuja Patel
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Clinical Pharmacology Reviewer	Edwin Chow
Nonclinical Team Leader	Whitney Helms
Nonclinical Reviewer	Stephanie Aungst
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Drug Product Quality Reviewer	Paresma Patel
Drug Substance Branch Chief	Kasturi Srinivasachar
Drug Substance Reviewer	Haripada Sarkar
CMC Microbiology Branch Chief	John Arigo
Microbiology Reviewers	Yarery Smith/ Jesse Wells
Facilities	Wendy Zhang/ Christina Cappaci-Daniel
Process Review Branch Chief	Rakhi Shah
Process Reviewer	Huiquan Wu
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\*Cross Discipline Team Leader (CDTL)