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APPLICATION NUMBER:

215133Orig1s000, 215133Orig2s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	March 15, 2021
Application Type and Number:	NDA 215133
Product Name and Strength:	(b) (4) capsules, 150 mg and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Almatica Pharma, LLC (Almatica)
PNR ID #:	2020-1044377285 and 2020-1044391747
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

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/s/

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