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APPLICATION NUMBER:
NDA 21-799

PHARMACOLOGY REVIEW(S)



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

PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA NUMBER: 21-799
SERIAL NUMBER: 000
DATE RECEIVED BY CENTER: 10/13/04
PRODUCT: Quinine Sulfate
INTENDED CLINICAL POPULATION: treatment of malaria (*P. falciparum*)
SPONSOR: Mutual Pharmaceutical Co., Inc.
DOCUMENTS REVIEWED: electronic submission
REVIEW DIVISION: Division of Special Pathogen and
Immunologic Drug Products (HFD-590)
PHARM/TOX REVIEWER: Steven Kunder, Ph.D.
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Date of review submission to Division File System (DFS):

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