

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-202

ENVIRONMENTAL ASSESSMENT and/or FONSI

NEW DRUG APPLICATION NDA #21-202  
METFORMIN HYDROCHLORIDE MODIFIED RELEASE TABLETS  
PART IV. ENVIRONMENTAL ASSESSMENT

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**Environmental Assessment**

Metformin Hydrochloride

The subject of the proposed action meets the requirements for a categorical exclusion from submitting an environmental assessment, 21 CFR 25.31(a). This action is not expected to increase the use of the active moiety metformin hydrochloride. In addition, to Bristol-Myers Squibb Company's knowledge, no extraordinary circumstances exist [21 CFR 25.15 (d)].

SEE CTRM  
REVIEW #1

APPEARS THIS WAY  
ON ORIGINAL