

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-178

**ENVIRONMENTAL ASSESSMENT and/or FONSI**

**PART IV. ENVIRONMENTAL ASSESSMENT**

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INITIAL NEW DRUG APPLICATION  
METFORMIN HYDROCHLORIDE-GLYBURIDE 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)].

Glyburide

The subject of the proposed action will not significantly affect the quality of the human environment and meets the requirements for a categorical exclusion from submitting an environmental assessment, 21 CFR 25.31(b). This action may increase the use of the active moiety glyburide, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. In addition, to Bristol-Myers Squibb Company's knowledge, no extraordinary circumstances exist [21 CFR 25.15 (d)].

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