CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-366/S-016

ENVIRONMENTAL ASSESSMENT



Environmental Assessment

Drug Substance

Rosuvastatin

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Environmental Assessment of Rosuvastatin

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AstraZeneca requests a categorical exclusion from the need to prepare an environmental assessment in accordance with 21 CFR 25.31 (a) or (b). To the best of the sponsor's knowledge, no extraordinary circumstances exist relative to this action.