

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022572Orig1s000

ENVIRONMENTAL ASSESSMENT



Mobius Therapeutics, LLC

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Environmental Analysis Requirement:

Categorical Exclusion (§ 25.31)

Pursuant to 21 CFR 25.31(a), action on a New Drug Application (NDA) is categorically excluded and does not require an Environmental Analysis or Environmental Impact Statement if the proposed action does not increase the use of the active moiety.

In addition, pursuant to 21 CFR 25.21, Mobius Therapeutics LLC states there are no extraordinary circumstances that may significantly affect the quality of the human environment.

Trabomycin™ Kit for Ophthalmic Use to be manufactured by Intas Pharmaceuticals, (b)(4) Gujarat, India (drug vial containing 0.2 mg/vial Mitomycin), and packaged and sterilized by Synergetics, Inc., O'Fallon, MO USA, will be administered at the dosage level 25 to 200 times less than the injection route via the topical route of administration as compared to the Reference Listed Drug for this submission, i.e., ANDA 062336 for Mutamycin Injectable 5 mg, 20 mg, 40 mg (Bristol Myers Squibb). The proposed drug product has been given an orphan-drug designation, with a potential patient population of fewer than 200,000 patients per year in the United States.

Therefore, Mobius Therapeutics, LLC hereby requests exclusion as specified in 21 CFR 25.31 (a) from the requirement to prepare an environmental assessment.

Mobius Therapeutics, LLC is also in full compliance with applicable local, state and federal environmental rules and regulations.

Ed Timm
President

Date: 22 Oct 09