CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-136

ENVIRONMENTAL ASSESSMENT and/or FONSI

C. ENVIRONMENTAL ASSESSMENT

Aura Laboratories, Inc. claims categorical exclusion from the requirement for an environmental assessment for the production of Lovastatin XL as per 21 CFR 25.31. The basis for this claim is that Lovastatin XL is a new dosage form that substitutes directly for an approved product. Aura Laboratories, Inc. certifies that:

Lovastatin XL is a new dosage form that substitutes directly for an approved product because the drug (i.e., the active moiety - lovastatin) will be used for the same indication, at the same or lower dosage levels (i.e., total daily dose), and for the same or shorter duration (e.g., number of days) as previously approved by the Agency for the same active moiety (i.e., lovastatin).

To the applicant's knowledge, no extraordinary circumstances exist, as defined in 21 CFR 25.15(d).

With regard to the production of Lovastatin XL, Aura Laboratories, Inc. certifies that it is in compliance with all applicable federal, state and local environmental regulations and laws.