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APPLICATION NUMBER:

sBLA 125057/110

ENVIRONMENTAL ASSESSMENT



BLA 125057

Humira® (adalimumab)

Supplemental BLA for Psoriasis

Environmental Assessment – Categorical Exclusion

The approval of this supplemental Biological License Application (BLA) for adalimumab will not significantly alter the concentration or distribution of this naturally occurring substance or its metabolites or degradation products. Abbott Laboratories therefore claims categorical exclusion from the requirement to prepare an Environmental Assessment, as provided in 21 CFR 25.31(c). As far as the applicant is aware, there are no extraordinary circumstances surrounding the approval of this supplemental BLA for adalimumab that could significantly affect the quality of the environment, and exclusion of adalimumab from the requirement for an Environmental Assessment is not rescinded under 21 CFR 25.21.

All manufacturing activities carried out in the United States, including the fermentation, clarification/capture, and purification of adalimumab, are in compliance with relevant federal, state, and local regulations.

The purpose of this supplemental BLA is to add a new indication to the labeling for Humira® (adalimumab) for the treatment of plaque psoriasis. It should be noted that this claim of categorical exclusion is the same as that contained in the original BLA for adalimumab, submitted March 28, 2002, as provided in CMC Volume 10, Page 318. The justification for this claim under the provisions of 21 CFR 25.31(c) will not be altered by the approval of this supplemental BLA.
