

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**BLA 125276/S049**

**ENVIRONMENTAL ASSESSMENT**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research

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**Date:** January 9, 2012

**From:** Gerald M. Feldman, Ph.D.  
Laboratory of Molecular and Developmental Immunology  
Division of Monoclonal Antibodies, CDER

**Subject:** BLA 125276.49: Categorical Exclusion for Environmental Assessment

**Through:** Marjorie Shapiro, PhD, Chief, LMDI, DMA, OBP, CDER.

**To:** BLA 125276.49 FILE

**Sponsor:** Hoffmann-La Roche Inc.

**Contact:** Kristine Ogozalek, Assoc Director, Drug Regulatory Affairs  
973-235-6227

**Date Submitted:** December 13, 2011  
**PDUFA Deadline:** October 12, 2012

This supplement is to expand the indication of tocilizumab (Actemra) for the treatment of patients who have had an inadequate response to [REDACTED] (b) (4) [REDACTED] active RA.

A categorical exclusion has been submitted under 21 CFR § 25.31(c). The applicant avers (Section 1.12.14 of the current submission) that the proposed action is not expected to significantly alter the concentration or distribution of the substance, its metabolites, or degradation products in the environment. No extraordinary circumstances exist that would significantly affect the quality of the human environment as a result of the proposed action or that would warrant the submission of additional environmental information.

**Reviewer's Comment:**  
**The Sponsor's claim of categorical exemption is accepted.**

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/s/  
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05/10/2012

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