

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125472Orig1s000

ENVIRONMENTAL ASSESSMENT



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

Date: January 24, 2013

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

Subject: BLA 125276.64: Categorical Exclusion for Environmental Assessment

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

To: BLA 125276.64 FILE

Sponsor: Hoffmann-La Roche Inc.

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

Date Submitted: June 28, 2012
PDUFA Deadline: April 29, 2013

This supplement is to expand the indication of tocilizumab (Actemra) for the treatment of patients 2 years of age and older who are suffering from polyarticular Juvenile Idiopathic Arthritis (pJIA).

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 acceptable.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GERALD M FELDMAN
03/19/2013

MARJORIE A SHAPIRO
03/20/2013