



Our STN: BL 103772/5113

Centocor, Incorporated
Attention: Stella S. Jones, PhD
Vice President, Worldwide Regulatory Affairs
200 Great Valley Parkway
Malvern, PA 19355-1307

SEP 15 2005

Dear Dr. Jones:

Your request to supplement your biologics license application for Infliximab to include a new indication for the treatment of patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response to conventional therapy, has been approved.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies until June 30, 2009.

We acknowledge your written commitments to to conduct postmarketing studies as described in your letter of September 2, 2005, as outlined below:

Postmarketing Studies subject to reporting requirements of 21 CFR 601.70.

1. Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 601.70. This commitment is listed below.
 - a. Deferred pediatric study under PREA for the treatment of moderately to severely active ulcerative colitis in pediatric patients.
 - b. Final protocol submitted to the IND: March 31, 2006
 - c. First patient enrolled in study: June 30, 2006
 - d. Last patient enrolled in study: December 31, 2007
 - e. Last patient out: December 31, 2008

f. Final Report Submission: June 30, 2009

Submit final study reports to this BLA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated “Required Pediatric Study Commitments”.

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted),
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment), and
- a revised schedule if the study schedule has changed and an explanation of the basis for the revision.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (<http://www.fda.gov/cder/pmc/default.htm>). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see <http://www.fda.gov/cber/gdlns/post040401.htm>) for further information.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the addresses for submissions.

Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

Sincerely,

A handwritten signature in black ink, appearing to read "Marc Walton", with a long horizontal flourish extending to the right.

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine
Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research