DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103772/5160

APR 19 2007

Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19335

Attention: Barbara Rake
Associate Director, Worldwide Regulatory Affairs

Dear Ms. Rake:

Your request dated and received June 20, 2006, to supplement your biologics license application for Remicade® (infliximab) to include safety information for Juvenile Rheumatoid Arthritis (JRA) in the label has been approved.

This also fulfills your commitment to conduct a Juvenile Rheumatoid Arthritis clinical study as stated in commitment number 3 of the November 10, 1999, approval letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and the text for the medication guide). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208, which you submitted with this supplement on February 12, 2007.

Please note that:

- this Medication Guide must be reprinted at the end of the package insert [21 CFR 201.57(f)(2)];
- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208];
- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided.

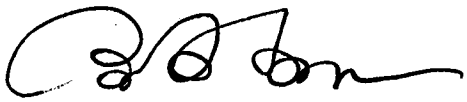
Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed 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.

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

Sincerely,



Bob A. Rappaport
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Children who took REMICADE in studies for Crohn's disease, showed some differences in side effects compared with adults who took REMICADE for Crohn's disease. The side effects that happened more in children were: anemia (low red blood cells), blood in stool, leukopenia (low white blood cells), flushing (redness or blushing), viral infections, neutropenia (low neutrophils, the white blood cells that fight infection), bone fracture, bacterial infection and allergic reactions of the breathing tract.

Tell your doctor about any side effect that bothers you or does not go away.

These are not all of the side effects with REMICADE. Ask your doctor or pharmacist for more information.

General information about REMICADE

Medicines are sometimes prescribed for purposes that are not mentioned in Medication Guides or patient information sheets. Do not use REMICADE for a condition for which it was not prescribed.

This information sheet summarizes the most important information about REMICADE. You can ask your doctor or pharmacist for information about REMICADE that is written for health professionals.

For more information go to www.remicade.com or call 1-800-457-6399.

What are the ingredients in REMICADE?

The active ingredient is Infliximab.
The inactive ingredients in REMICADE include: sucrose, polysorbate 80, monobasic sodium phosphate monohydrate, and dibasic sodium phosphate dihydrate. No Preservatives are present.

Product developed and manufactured by:
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355

Revised April 2007

This Medication Guide has been approved by the U.S. Food and Drug Administration.