CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205776Orig1s000

Trade Name:	Rasuvo 7.5 mg/0.15 mL, 10 mg/0.20 mL, 12.5 mg/0.25 mL, 15 mg/0.30 mL, 17.5 mg/0.35 mL, 20 mg/0.40 mL, 22.5 mg/0.45mL, 25 mg/0.50 mL, 27.5 mg/0.55 mL, and 30 mg/0.60 mL.
Generic Name:	methotrexate injection
Sponsor:	Medac Pharma, Inc.
Approval Date:	July 10, 2014
Indication:	For the management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), and for symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205776

NDA APPROVAL

Medac Pharma, Inc.
c/o B&H Consulting Services, Inc.
50 Division Street, Suite 206
Somerville, NJ 08876

Attention: Stephanie Pierson, RAC
Vice President

Dear Ms. Pierson:

Please refer to your New Drug Application (NDA) dated September 10, 2013, received September 10, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rasuvo (methotrexate injection) 7.5 mg/0.15 mL, 10 mg/0.20 mL, 12.5 mg/0.25 mL, 15 mg/0.30 mL, 17.5 mg/0.35 mL, 20 mg/0.40 mL, 22.5 mg/0.45mL, 25 mg/0.50 mL, 27.5 mg/0.55 mL, and 30 mg/0.60 mL.

We acknowledge receipt of your amendments dated December 20, 2013, and January 10, 15, 16, and 23, February 25 and 28, March 21, April 3, 4, 8, 17, and 30, May 6, 9, 16, 23, 28, and 29, and June 4, 12, 17, and July 3, 2014.

This new drug application provides for the use of Rasuvo (methotrexate injection) for the management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), and for symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

EXPIRATION DATING PERIOD

A 17-month expiry dating period is granted for Rasuvo (methotrexate injection) when stored at controlled room temperature between 20°C and 25°C (68°F and 77°F) with excursions permitted from 15°C and 30°C (59°F and 86°F).

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, text for instructions for use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 205776**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 through 2 years for pJIA because the disease is extremely rare in this age group and studies would be impossible or highly impractical.

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