

Arthritis Advisory Committee
Food and Drug Administration
Center for Drug Evaluation and Research

August 7, 1998
Holiday Inn Bethesda
8120 Wisconsin Avenue, Bethesda, MD

NDA 20-905, leflunomide, Hoechst Marion Roussel

Questions

1. Should leflunomide be approved for relief of signs and symptoms of rheumatoid arthritis?
2. Should leflunomide be approved for clinically significant retardation of structural damage in rheumatoid arthritis?
3. Should leflunomide be approved at this point for prevention of disability?
4. Does the risk of the use of leflunomide in pregnant women clearly outweigh any possible benefit?
5. What advice should be given to a woman who has been taking leflunomide and wishes to become pregnant, or for a man taking leflunomide who wishes to become a father?
6. What information should be provided about the risk of liver toxicity? What type and frequency of monitoring should be recommended? How should treatment be modified based on monitoring?
7. What should be advised about the use of leflunomide in patients with hepatic insufficiency or other liver disease?
8. What information should be provided about the risk of malignancy?
9. Are additional clinical studies needed to further evaluate leflunomide efficacy and/or safety in rheumatoid arthritis? If so, what studies are recommended?