BLOOD PRODUCTS ADVISORY COMMITTEE
84th Meeting – September 29, 2005
CDER Advisory Committee Conference Room
5630 Fishers Lane, Rockville, Maryland

DRAFT AGENDA as of Sept 19, 2005

The Blood Products Advisory Committee (BPAC) will discuss new drug application (NDA) 21-882, proposed trade name Exjade (deferasirox) Tablets for Oral Suspension, Novartis Pharmaceutical Corporation, for the proposed indication of the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Following this discussion, the committee will hear an overview of the research programs in the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review, CBER, and in closed session will discuss the report from the laboratory site visit of Feb 25, 2005.

8:00 a.m.	Welcome, Statement of Conflict of Interest, Announcements	James R. Allen, M.D., M.P.H. Chair, BPAC Donald W. Jehn, M.S. Executive Secretary, BPAC

TOPIC I: NDA 21-882

8:10 a.m. FDA Introduction, George Mills, M.D., Director, Division of Medical Imaging and Hematology Products, CDER, FDA

8:15 a.m. Sponsor Presentations, Novartis Pharmaceutical Corp.

- Introduction, P.K. Narang, Ph.D., Vice President, Global Head Drug Regulatory Affairs, Oncology Business Unit, Novartis
- Burden of Disease, Professor John Porter, University College London, Department of Hematology, UK
- Efficacy and Safety Data, Peter Marks, M.D., Ph.D., Senior Director, Oncology Business Unit, Novartis
- Conclusions on Benefit and Risk, Elliott Vichinsky, M.D., Children's Hospital and Research Center at Oakland, Department of Hematology/Oncology, Oakland, CA

9:45 a.m. Questions and Answers

10:00 a.m. Break

10:15 a.m. FDA Presentation, George G. Shashaty, M.D., Medical Officer, CDER, FDA

11:00 a.m. Questions and Answers

11:15 a.m. Open Public Hearing

12:15 p.m. Lunch

Blood Products Advisory Committee

September 29, 2005

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1:15 p.m. Questions to Committee & Discussion

3:15 p.m Adjourn Topic I / Break

TOPIC II: Review of Research Program Site Visit, Division of Hematology, OBRR/CBER

3:30 p.m. Laboratory Presentations

Hira Nakhasi, Ph.D., Acting Associate Director for Science, OBRR, CBER, FDA (5')
Basal Golding, M.D., Director, DH, OBRR , CBER, FDA (5')
Principle Investigators in the Laboratory of Plasma Derivatives (LPD):
Basil Golding, M.D., Chief, Immunology Section 1 (5')
Dorothy Scott, M.D., Chief, LPD, Immunology Section 2, DH, OBRR, CBER, FDA (5')
Mei-ying Yu, Ph.D., Safety and Quality Control Section, DH, OBRR, CBER, FDA (5')
Principle Investigators in the Laboratory of Hemostasis (LH):
Jay Lozier, M.D., Ph.D., Senior Staff Fellow, Laboratory of Hemostasis, DH, OBRR, CBER, FDA (5')

4:05 p.m. Break to Clear Room for Closed Session

4:15 p.m. Closed Session

5:00 p.m. Adjourn