Medical Imaging Drugs Advisory Committee

Food and Drug Administration Center for Drug Evaluation and Research

Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda MD

Biologic License Application (BLA) 99-1407, Leutech™ (Technicium labeled TC99M anti/CD15 antibody injection), Palatin Technologies Inc.

Agenda for July 10, 2000

8:30 Call to Order, Introductions: Laura L. Boles Ponto, Ph.D., Chair

Meeting Statement: Thomas H. Perez, M.P.H., Executive Secretary

8:45 Palatin Technologies Inc. Presentation:

Introduction Charles Putnam, Chief Operating Officer, Palatin

Description of LeuTech Terry Smith, Ph. D., Executive Director, Product Development, Palatin

Equivocal Appendicitis Eric Rypins, M.D. Department of Surgery, Tri-City Medical Ctr.

Imaging Techniques & Interpretation Samuel Kipper, M.D. Director Nuclear Medicine, Tri-City Medical Ctr.

Clinical Development Program Karen McElvany, Ph.D. Director Clinical Affairs, Certus International Inc.

Conclusion Charles Putnam, Chief Operating Officer, Palatin

9:30 FDA Presentation:

Products Review Chana Fuchs

Nuclear Medicine Lydia Martynec

Clinical Review Robert Lindblad

10:15 Break

10:30 Open Public Hearing

11:30 Charge to the Committee, Introduction to Questions and Initial Discussion

12:00 Lunch

1:30 Discussion and Questions (continued)

2:30 Adjourn

Invited Guest Experts and Consultants

Robert Rothstein, M.D., Director of Emergency Medicine at Suburban Hospital, Bethesda, MD Gary Strange, M.D., Director of Emergency Medicine at University of Illinois, Chicago, IL Eddie Hoover, M.D., State University of New York Thomas Whalen, M.D., Robert Wood Johnson Medical School at Camden Brent Blumenstein, Ph.D., American College of Surgeons - Oncology Group