

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Silver Spring, Maryland
April 2, 2009

AGENDA

*The committee will discuss NDA 22-341, liraglutide injection, Novo Nordisk, Inc.,
proposed for treatment of hyperglycemia in adults with type 2 diabetes mellitus.*

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| 8:00 a.m.– 8:05 a.m. | Call to Order and Introductions | Kenneth Burman, M.D.
Committee Chair
Endocrinologic and Metabolic Drugs Advisory
Committee (EMDAC) |
| 8:05 a.m. – 8:15 a.m. | Conflict of Interest Statement | Paul Tran, R.Ph.
Designated Federal Official
EMDAC |
| 8:15 a.m. – 9:45 a.m. | Sponsor Presentation | Novo Nordisk Inc. |
| 9:45 a.m. – 10:00 a.m. | Clarifying Questions From the
Committee to Sponsor | |
| 10:00 a.m. – 10:15 a.m. | Break | |
| 10:15 a.m. – 10:45 a.m. | FDA Presentation
Pharmacology-Toxicology | Anthony Parola, Ph.D.
Pharmacology/Toxicology Reviewer
Center for Drug Evaluation and Research (CDER)
Division of Metabolism and Endocrinology Products
(DMEP) |
| 10:45 a.m. – 11:00 a.m. | Clarifying Questions From the
Committee to Dr. Parola | |
| 11:00 a.m. – 11:45 a.m. | FDA Presentation
Clinical | Karen Mahoney, M.D.
Clinical Reviewer
CDER, DMEP |
| | | Janice Derr, Ph.D.
Statistical Reviewer
CDER, Office of Biostatistics |
| 11:45 a.m. – 12:00 p.m. | Clarifying Questions From the
Committee to Drs. Mahoney
and Derr | |
| 12:00 p.m. – 1:00 p.m. | Lunch | |

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| 1:00 p.m. – 2:00 p.m. | Open Public Hearing Session |
| 2:00 p.m. – 2:30 p.m. | Questions From the Committee
to Sponsor and FDA |
| 2:30 p.m. – 2:45 p.m. | Break |
| 2:45 p.m. – 5:00 p.m. | Discussion/Questions to the
Committee |
| 5:00 p.m. | Adjourn |

DRAFT