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**APPLICATION NUMBER:** 

201280Orig1s000

**MEDICAL REVIEW(S)** 



### **CLINICAL REVIEW**

APPLICATION TYPE NDA

APPLICATION | 201280

NUMBER(S)

PRIORITY OR S

STANDARD

SUBMIT DATE(S) JULY 2, 2010

**RECEIVED DATE(S)** JULY 2, 2010

PDUFA GOAL DATE MAY 2, 2011

**DIVISION / OFFICE DIVISION OF METABOLISM** 

AND ENDOCRINOLOGY PRODUCTS/OFFICE OF

**NEW DRUGS II** 

REVIEWER NAME(S) SOMYA VERMA DUNN
REVIEW COMPLETION MARCH 11, 2011
DATE

ESTABLISHED NAME LINAGLIPTIN
(PROPOSED) TRADE
NAME



THERAPEUTIC CLASS DIPEPTIDYL-PEPTIDASE

**INHIBITOR** 

APPLICANT BOEHRINGER INGELHEIM

PHARMACEUTICALS, INC.

FORMULATION(S) ORAL TABLET

**DOSING REGIMEN 5 MG DAILY** 

INDICATION(S) TREATMENT OF TYPE 2

**DIABETES** 

INTENDED ADULTS

POPULATION(S)

Template Version: March 6, 2009



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