

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

201281Orig1s000

ENVIRONMENTAL ASSESSMENT

Section 1.14.1.1 in the labeling section of the electronic submission indicates that there are both draft carton and container labels in the submission. However, only container (bottle) labels were provided. The firm should explain this discrepancy and provide the carton labels, if appropriate.

Comments to be Communicated to the Applicant

Section 1.14.1.1 in the labeling section of the electronic submission indicates that there are both draft carton and container labels in the submission. However, only container (bottle) labels were provided. You should explain this discrepancy and provide the carton labels, if appropriate.

Since the product needs to be protected from high humidity, your immediate container labels should contain a brief statement about the need to keep the desiccant packet in the bottle after opening.

Structure Product Labeling (SPL)

Structure Product Labeling, at the end of the package insert will be reviewed at a later date.

ENVIRONMENTAL ASSESSMENT

The firm requests a Categorical Exclusion (waiver) from the preparation of an Environmental Assessment under 21CFR§25.31(a) and (b), since the estimated concentration of linagliptin at the point of entry into the aquatic environment will be below 1 part per billion. The claim for a Categorical Exclusion for metformin HCl is based on 21CFR§25.31(a) because they claim approval would not increase the use of this previously approved drug since it is expected that those patients switching to linagliptin/metformin HCl tablets will no longer use other previously approved products containing metformin HCl.

Evaluation:

The request for the waiver is acceptable