



NDA 216778/S-003

APPROVAL LETTER

ZyduS Lifesciences Global FZE
c/o ZyduS Pharmaceuticals USA Inc.
Attention: Srinivas (Srini) Gurram
Sr.VP- Head-RA&CQA lead
73-B Route 31 North
Pennington, NJ 08534

Dear Srinivas (Srini) Gurram:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 20, 2025, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZITUVIMETXR (sitagliptin and metformin hydrochloride) extended release tablets 50 mg/500 mg, 50 mg/1000 mg, and 100 mg/1000 mg.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the addition of 90-count for 100 mg/1000 mg and 180-count for 50 mg/500 mg and 50 mg/1000 mg high-density polyethylene (HDPE) bottle pack sizes for sitagliptin and metformin hydrochloride extended-release tablets, a change in the desiccant, and updates to prescribing information (PI), medication guide, and container labels.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your March 25, 2026, submission includes final printed labeling (FPL) for your prescribing information, and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

We acknowledge your March 25, 2026, submission containing final printed carton and container labeling.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third

parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.¹

If you have any questions, contact Emma Gimose, Regulatory Business Process Manager, at emma.gimose@fda.hhs.gov or (240) 402 - 1681.

Sincerely,

{See appended electronic signature page}

David Claffey, Ph.D.
Supervisor
Division of Product Quality Assessment III
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

¹ <https://www.uspnf.com/>

Enclosure(s):

Content of Labeling

Carton and Container Labeling



Hasmukh
Patel

Digitally signed by Hasmukh Patel

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