

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

090533Orig1s015

Trade Name: Zenzedi

Generic or Proper Name: Dextroamphetamine Sulfate

Sponsor: Azurity Pharmaceuticals, Inc.

Approval Date: October 28, 2025

Indication: For treatment of attention-deficit hyperactivity disorder and narcolepsy.



ANDA 090533/S-015

**PRIOR APPROVAL SUPPLEMENT
APPROVAL**

Azurity Pharmaceuticals, Inc.
8 Cabot Road
Suite 2000
Woburn, MA 01801
Attention: Nagarjuna Brahmanapalle
Senior Manager, Regulatory Affairs

Dear Nagarjuna Brahmanapalle:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on May 8, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dextroamphetamine Sulfate Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as "Prior Approval Supplement," provides for:

Changes to the approved stability protocol: Removal of 3, 6, 9 and 18 months stability time points for long-term CRT stability study from the post-approval stability protocol for Dextroamphetamine Sulfate Tablets USP.

We have completed the review of this sANDA, as amended, and it is **approved**.

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 standard 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 as <https://www.uspnf.com/>.

U.S. Food & Drug Administration
Silver Spring, MD 20993
www.fda.gov

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

If you have any questions, contact Theresa (Terri) Shamis, Regulatory Business Process Manager, at (301) 796 - 7249 or theresa.shamis@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:

Yue Teng, Ph.D.

Director

Division of Product Quality Assessment V

Office of Product Quality Assessment I

Office of Pharmaceutical Quality

Center for Drug Evaluation and Research



Robert
Berendt

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Disciplines Involved	Outcome	Disciplines Involved	Outcome
Chemistry	Adequate	Biopharmaceutics	N/A
Microbiology	N/A	Bioequivalence	N/A
Facilities	N/A	DMF (Chemistry)	N/A
Labeling	N/A	DMF (Microbiology)	N/A
Submissions Assessed			
Received Date:	5/8/2025		
Amendment(s) Date:	10/01/2025		

OFFICE OF PHARMACEUTICAL QUALITY
ASSESSMENT OF SUPPLEMENT TO ABBREVIATED NEW DRUG APPLICATION

Chemistry Assessment Number : 01

ANDA/Supplement Number : 090533/S-15

Drug Product Name, Strength : Dextroamphetamine Sulfate Tablets, 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg

Pharmacological Category/ Indication(s) : For treatment of attention-deficit hyperactivity disorder, and narcolepsy

Applicant Name (or US Agent if Applicable) : Azurity Pharmaceuticals, Inc.

Supplement Provides For : Changes to the approved stability protocol: Removal of 3, 6, 9 & 18 months stability time points for long-term CRT stability study from the post-approval stability protocol for Dextroamphetamine Sulfate Tablets, USP.

Filing Category with basis for decision/comments (based on guidance for industry/CFR quotes) : PAS

Relevant Supporting DMF(s) Cited (If Applicable)

DMF No.	DMF	Result of Assessment	Date Assessment Completed
N/A	Comment (if any) on DMF Assessment, Assessor		

ASSESSMENT NOTES

The applicant has submitted this Prior Approval Supplement to propose removal of 3-, 6-, 9- & 18-months stability time points for long-term CRT stability study from the post-approval stability protocol for Dextroamphetamine Sulfate Tablets, USP, ANDA 090533.

Information Provided by Applicant

Table 1. Currently approved stability protocol

Drug Product	Pack Configuration	Phase	Conditions	Stations (months)
Dextroamphetamine Sulfate Tablets, USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 30 mg	30's & 100's HDPE Packs	Long Term	25°C ± 2°C / 60% ± 5% RH	0, 3, 6, 9, 12, 18, 24 & 36

Table 2. Proposed stability protocol

Drug Product	Pack Configuration	Phase	Conditions	Stations (months)
Dextroamphetamine Sulfate Tablets, USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 30 mg	30's & 100's HDPE Packs	Long Term	25°C ± 2°C / 60% ± 5% RH	0, 12, 24 & 36

In compliance with the FDA recommendation to Industry dated October 18, 1985, on Expiration Dating and Stability Testing for Human Drug Products, once the tentative expiration date for the drug product has been confirmed via approved stability protocol, reduced testing may be acceptable, provided sufficient data was generated. As per point # B3 (Testing interval) of above FDA's reference, testing at least annually (i.e., every 12 months) is considered minimal for compliance with CGMPs. However, Azurity adopted the following approach based on the assigned shelf life.

(b)(4)

The stability study up to 36 months (expiration) has been completed for multiple drug product batches. All the data through 36 months are within the specification limit and there was no adverse trend observed for any of the parameters.

The stability compilation sheets for batches have been provided in section 3.2.P.8.3 of Seq # 0013, Seq # 0016, Seq # 0020, Seq # 0025 and Seq # 0030.

Based on the historical data, there is no risk in eliminating 3, 6, 9 and 18 month stability time points from the post-approval stability protocol.

Azurity Pharmaceuticals Inc. (Azurity) hereby commits to submit the revised stability protocols for all strengths upon approval of this supplement in subsequent submissions.

Reviewer's Assessment: Adequate

From FDA inspection guide "Expiration Dating and Stability Testing for Human Drugs STABILITY TESTING (21 CFR 211.166) B.3", it is stated that testing at least annually is considered minimal for compliance with CGMPs. The applicant cited this guidance and their completed 36 months stability studies for multiple batches to support proposed stability time points of 0, 12, 24 & 36 months.

The applicant did not submit trending and graphical presentation of data from stability batches to support the omission of 3M, 6M, 9M & 18-months stability time points for long-term CRT stability study from the post-approval stability protocol for Dextroamphetamine Sulfate Tablets, USP, ANDA 090533. Resolved in IR response (Seq.0034,10/01/2025). Applicant provided the data requested, see assessment below.

IR Deficiency #1:

We acknowledge that you reference section 3.2.P.8.3 of Seq # 0013, Seq # 0016, Seq # 0020, Seq # 0025 and Seq # 0030 for the summary of the stability data. However, the submission does not include stability trend data and graphical presentations for all quality attributes in the stability specification. To support your proposed reduction in stability time points, you should demonstrate the stability profile of the drug product as recommended in ICH Q1A(R2) *Stability Testing of New Drug Substances and Products (February 2003)* and evaluate observed trends. Please submit in table format a list of all batches placed on stability and specify the manufacturing date. In addition, provide stability trend data of all the quality attributes in the stability specification (organoleptic, assay, related substances, dissolution, [REDACTED] hardness, and water), graphical presentation for all stability results, and a narrative of data evaluation to support your proposed reduction in stability time points.

IR Response (Seq.0034, 10/01/2025)

As per the Agency's recommendation, a list of drug product batches completed the 36-month stability period that are submitted in Section 3.2.P.8.3 of seq # 0013, Seq # 0016, Seq # 0020, Seq # 0025 and Seq # 0030 are provided specifying the manufacturing dates. In addition, stability summary and stability trend data of all the quality attributes in the stability specification (organoleptic, assay, related substances, dissolution, [REDACTED] hardness, and water), graphical presentation for all stability results, and a narrative of data evaluation to support our proposed reduction in stability time points is provided in section 3.2.P.8.1 of this submission.

Assessment of Response: Acceptable

The submitted stability summary and stability trend data of all the quality attributes in the stability specification (organoleptic, assay, related substances, dissolution, [REDACTED] hardness, and water) and the graphical presentation for all stability results from completed [REDACTED] - months stability (2.5 mg , 5 mg, 7.5 mg, 10 mg, 20 mg and 30 mg drug product strength; 30's and 100's packaging) showed no specific stability trend and complies to stability specifications. These data results supported the applicant's proposal remove 3, 6, 9 & 18 months stability time points for long-term CRT stability study from the post-approval stability protocol for Dextroamphetamine Sulfate Tablets, USP.

IR Deficiency #2:

Please provide your proposed stability protocol for all strengths in section 3.2.P.8.2. To ensure adequate stability data are available to support future post-approval changes, the protocol should include a statement to confirm that for significant changes for which drug product stability studies are warranted, you will submit full stability results, i.e., long-term study results based on the originally approved testing intervals (Initial, 3, 6, 9, 12, 18, 24 months) as recommended in ICH Q1A(R2) *Stability Testing of New Drug Substances and Products (February 2003)*.

IR Response (Seq.0034,10/01/2025)

As recommended by the Agency, the post-approval stability protocols have been revised to retain the originally approved testing intervals (Initial, 3, 6, 9, 12, 18, 24, and 36 months) for significant changes under controlled room temperature stability testing program. Additionally, reduced testing intervals (Initial, 12, 24 and 36 months) have been proposed for routine stability testing of the drug product. The proposed post-approval stability protocols are provided in section 3.2.P.8.2 of this submission.

Assessment of Response: Acceptable

The updated stability protocol specified routine stability test intervals as initial, 12, 24, and 36 months and test intervals for significant changes as initial, 3, 6, 9, 12, 18, 24 and 36 months for all drug product strengths.

RECOMMENDATION

- Supplement is CMC Approvable
- Supplement is NOT CMC Approvable (with brief explanation:)

(Choose IR, CR-Minor, CR-Major); Deficiencies noted below:

Deficiencies to be communicated: None

Primary Assessor : Maryann Cunanan

Date :09/08/2025;10/01/2025



Maryann
Cunanan

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Pineiro Sanchez

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Date: 10/14/2025 02:32:19PM
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ANDA 090533/S-015

**INFORMATION REQUEST
QUALITY**

Azurity Pharmaceuticals, Inc.
8 Cabot Road, Suite 2000
Woburn, MA 01801
Attention: Nagarjuna Brahmanapalle
Senior Manager, Regulatory Affairs

Dear Nagarjuna Brahmanapalle:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on May 8, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dextroamphetamine Sulfate Tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg.

We are reviewing the Quality section of your submission and have the following comments and information requests:

A. Drug Product

1. We acknowledge that you reference section 3.2.P.8.3 of Seq # 0013, Seq # 0016, Seq # 0020, Seq # 0025 and Seq # 0030 for the summary of the stability data. However, the submission does not include stability trend data and graphical presentations for all quality attributes in the stability specification. To support your proposed reduction in stability time points, you should demonstrate the stability profile of the drug product as recommended in ICH Q1A(R2) Stability Testing of New Drug Substances and Products (February 2003) and evaluate observed trends. Please submit in table format a list of all batches placed on stability and specify the manufacturing date. In addition, provide stability trend data of all the quality attributes in the stability specification (organoleptic, assay, related substances, dissolution, hardness, and water), graphical presentation for all stability results, and a narrative of data evaluation to support your proposed reduction in stability time points.
2. Please provide your proposed stability protocol for all strengths in section 3.2.P.8.2. To ensure adequate stability data are available to support future post-approval changes, the protocol should include a statement to confirm that for significant changes for which drug product stability studies are warranted, you will submit full stability results, i.e., long-term study results based on the originally approved testing intervals (Initial, 3, 6, 9, 12, 18, 24 months) as recommended in ICH Q1A(R2) Stability Testing of New Drug Substances and Products (February 2003).

U.S. Food & Drug Administration
Silver Spring, MD 20993
www.fda.gov

We request a prompt written response, no later than September 24, 2025, in order to continue our evaluation of your ANDA. We will not process or review a partial response. Facsimile or e-mail responses will also not be accepted. In addition, if your response contains either gratuitous information not requested by FDA or information that requires a more thorough review as determined by FDA, FDA may classify the response as an amendment and assign an appropriate goal date for that amendment. The goal date assigned to the amendment may extend the review goal date for your current submission.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

**INFORMATION REQUEST
QUALITY**

If you have any questions, please contact Theresa (Terri) Shamis, Regulatory Business Process Manager, at theresa.shamis@fda.hhs.gov or (301) 796 - 7249.

Sincerely,

{See appended electronic signature page}

On behalf of:
Theresa (Terri) Shamis
Regulatory Business Process Manager
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Jeena
Amaya

Digitally signed by Jeena Amaya
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