



ANDA 200959/S-007

**CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL**

Arthur Group LLC
9 Deerpark Drive
Suite J-3
Monmouth Junction, NJ 08852-1976
Attention: Isaac Liu
Chief Executive Officer

Dear Isaac Liu:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on March 10, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Sevelamer Carbonate Tablets, 800 mg.

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

The sANDA, submitted as "Changes Being Effected in 30 Days," provides for:

Additional laboratory testing functions of Bora Pharmaceutical Laboratories Inc. (FEI: 30078184570) for both Sevelamer Carbonate substance and drug product Tablets, 800 mg.

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/>.

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 further questions regarding this supplement, you may contact Rachelle St. Fleur, Regulatory Business Process Manager, at (301) 348 - 1577.

Sincerely yours,

{See appended electronic signature page}

For:

Paul Schwartz, Ph.D.
Director, Division of Post Marketing Activities II
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



Karen
Bernard

Digitally signed by Karen Bernard

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