FDA Compliant Repackaged Avastin® for Retinal Diseases.

Leiters.

COMPOUNDING HEALTH™

There is more than meets the eye when using Avastin that is not repackaged under the new FDA guidance.

Now you have a better choice....Leiters can provide repackaged Avastin that is compliant with the new FDA guidance.[1]

Leiters Takes the Lead in Repackaging Avastin for Retinal Diseases

In an era of rapid regulatory change and heightened demand for high quality, compounded and repackaged drugs, Leiters, an FDA-registered 503B outsourcer, has emerged as a leader.

Specializing in ophthalmology and hospital-based services, Leiters provides repackaged Avastin in accordance with the Food and Drug Administration's 2018 Final Guidance for the Repackaging of Biologics.

The Leiters' Difference Makes a Difference for your Patients

- FDA compliant
- USP <789> compliant for visible and subvisible particles
- Batch release testing for sterility, endotoxin, color and clarity, visible particles and subvisible particles
- A Certificate of Analysis (CoA) is provided with every shipment
- Repackaged in a silicone free syringe
- Repackaging process that includes an optimized aseptic technique process
- cGMP compliance that ensures the biologic product maintains appropriate package integrity during shipping

Footnotes

[1] Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry https://www.fda.gov/downloads/drugs/guidances/ucm434176.pdf

STERILE, REPACKAGED

Avastin (bevacizumab)

PRESERVATIVE-FREE

Leiters.

NDC	70360-001-02	70360-001-60
Description	Avastin (bevacizumab) 2.5 mg/0.1 mL repackaged, Intravitreal injection, 0.1 mL in a 1 mL syringe	Avastin (bevacizumab) 3.25mg/0.13 mL repackaged, Intravitreal injection, 0.13 mL in a 1 mL syringe
Unit size	0.1 mL in a 1 mL syringe	0.13 mL in a 1 mL syringe
Storage	Refrigerate; protect from light & freezing	Refrigerate; protect from light & freezing
Beyond Use Date	90 days	90 days

FDA Biologic Repackaging Guidance[1]

- ✓ Assigned 90-day BUD in accordance with FDA's Guidance for Industry

Stability Testing:

- ✓ Appearance
- ✓ Color and Clarity
- ✓ Visible Particles
- ✓ Subvisible particles, USP <789>
- ✓ Protein Content, USP <1057>
- ✓ Protein-related impurities, including protein aggregation, size, and charge variants
- ✓ Potency, stability-indicating
- ✓ Sterility, USP <71>

Batch Release Testing:

- ✓ Sterility, USP <71>
- ✓ Endotoxin, USP <85>
- ✓ Color and Clarity
- ✓ Visible particulates
- ✓ Subvisible particles, USP <789>

To place an order call **800.292.6772** or email **orders@leiters.com**

To learn more visit us at **www.leiters.com**

Leiters.

COMPOUNDING HEALTH™

Leiters is a trusted FDA-registered 503B outsourcing provider of high quality ophthalmology and hospital-based services. We are committed to providing healthcare professionals and their patients with high quality medications. Our team of experts in sterile pharmaceutical manufacturing, repackaging, and pharmacy provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in outsourcing. We combine our team, our robust processes and our state-of-the art outsourcing facilities to ensure the highest quality products and services. We believe the most important consumer of our products are patients, and patients have trusted Leiters with their health for nearly a century.