Leiters.

COMPOUNDING HEALTH™

FDA Compliant Repackaged Avastin® for Retinal Diseases.

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 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 compounded sterile preparations, 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 particulates
- Batch release testing for sterility, endotoxin, color and clarity, visible particulates and subvisible particulates
- 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

Quality. Compliance. Consistency.

Leiters.

STERILE, REPACKAGED / PRESERVATIVE-FREE

Avastin (bevacizumab)

NDC	71449-091-43	71449-091-44
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 particulates
- ✓ Subvisible particulates, USP <789>
- ✓ Protein content, USP <1057>
- ✓ Product-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 particulates, USP <789>

USP <789> is the lowest level particulate standard which the FDA expects for ophthalmic solutions.

Orders & Inquiries ☎ 800.292.6772 🌐 www.leiters.com ✉ info@leiters.com

Leiters, founded in 1926, is a trusted FDA-registered 503B outsourcing provider of high-quality hospital and ophthalmology compounded sterile preparations. We are committed to providing healthcare professionals and their patients with high quality outsourced medications. Our team of experts in sterile pharmaceutical manufacturing, repackaging and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in pharmaceutical outsourcing. We combine a highly experienced team, with robust processes, in a new state-of-the-art outsourcing facility, to ensure delivery of the highest quality medicines. All sterile preparations are produced under the Human Drug Outsourcing Facilities under 503B of the FD&C Act (503B Guidance) and follow Current Good Manufacturing Practices (cGMP). To learn more about how we're Compounding Health™ please visit www.leiters.com

Leiters | 13796 Compark Boulevard | Englewood, Colorado 80112

 [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