BIOPHARMA PEG Achieves FDA DMF Listings for Two PEG Derivatives

Two PEG-based intermediates from BIOPHARMA PEG now listed in FDA DMF, supporting regulatory needs for drug delivery and bioconjugation.

Biopharma PEG

WATERTOWN, MA, UNITED STATES, July 18, 2025 /EINPresswire.com/ -- BIOPHARMA PEG, a developer of functional polyethylene glycol (PEG) derivatives for pharmaceutical R&D, has announced that two of its PEG-based intermediates have been assigned Drug Master File (DMF) numbers by the U.S. Food and Drug Administration (FDA).

The products now listed in the FDA's DMF system are:
- mPEG-pALD (20K) – DMF No. 040600
- HZ-PEG-HZ (1K) – DMF No. 041864

These compounds are used widely in drug conjugation, hydrogel crosslinking, and nanoparticle surface modification. The DMF filings support regulatory documentation for use in preclinical and clinical drug development programs.

PEG Derivatives for Bioconjugation and Delivery
Developed by BIOPHARMA PEG, the two intermediates offer functional groups useful in targeted bioconjugation strategies:
- mPEG-pALD (20K) is a methoxy-terminated PEG with a reactive aldehyde group, suitable for forming stable covalent bonds with primary amines. It is commonly used in PEGylation of proteins, peptides, and antibody-drug conjugates (ADCs), where stability and precision in conjugation are critical.
- HZ-PEG-HZ (1K) features two terminal hydrazide groups, which selectively react with aldehyde or ketone functionalities under mild conditions. This product is particularly relevant in hydrogel synthesis and macromolecular crosslinking, offering flexibility for both research and therapeutic

applications.

Regulatory Readiness for Advanced Therapeutics
The availability of Type IV DMFs enables BIOPHARMA PEG's partners and clients to reference these materials directly in regulatory filings, supporting compliance with FDA expectations for raw materials in biologics and complex drug products.
PEG-based linkers remain core components in the design of advanced drug delivery systems, enabling enhanced pharmacokinetics, reduced immunogenicity, and controlled release profiles. These recent filings reflect BIOPHARMA PEG’s commitment to providing high-purity, well-documented PEG reagents that meet evolving industry standards.

For more information or to request a letter of authorization (LOA):
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About BIOPHARMA PEG:
BIOPHARMA PEG is a global leader in the design, synthesis, and manufacture of high-purity polyethylene glycol (PEG) derivatives. Driven by a mission to accelerate drug discovery and development, BIOPHARMA PEG provides PEG derivatives that enhance the therapeutic profile of pharmaceuticals, improve patient outcomes, and push the boundaries of medical innovation.

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