



Novozymes Biopharma sets gold standard as suppliers of world's first USP-NF compliant recombinant human albumins

Nottingham, UK (May 1 2009) Novozymes Biopharma, part of Novozymes, the world leader in bioinnovation, today announced that its Recombumin[®] and albucult[®] products are the first to comply with the new excipient monograph standard for recombinant human albumin, published in the United States Pharmacopoeia – National Formulary (USP-NF). The monograph was first published in November 2008 and became official on 1st May 2009. As these products comply with the monograph, their use eases the regulatory process for customers and sets the industry benchmark for recombinant human albumin.

Recombumin offers the stabilizing and formulation benefits of human derived albumin in a GMP compliant and regulatory friendly package. Derived from Novozymes' proprietary yeast expression technology, it is the world's leading animal-free, commercially available recombinant human albumin for use in the manufacture of licensed and developmental human therapeutics in the US and European markets. albucult is also a yeast-derived recombinant albumin, targeted for use in specialized cell culture and as a bulk drug manufacturing raw material, such as in peptide or small molecule drug chemical coupling for delivery or half-life extension.

Wayne Prestwood, Principal Regulatory Associate at Novozymes Biopharma comments, "We are delighted to be setting the gold standard with our Recombumin and albucult products by being the first to comply with the new monograph. This is of significant benefit to our customers, providing peace of mind whilst facilitating regulatory agency review and approval."

The monograph refers to recombinant human albumin as "rAlbumin Human NF" listed as a "sterile vehicle" meaning that it is intended for injection into humans alongside the active ingredient, and as such needs to be of the highest safety and quality. The monograph is available to USP-NF subscribers and can be accessed at <http://www.uspnf.com/uspnf/login>

Novozymes Biopharma offers a range of technologies and animal-free recombinant supplements and ingredients. Its portfolio of biological solutions includes albumin fusion technology (albufuse[®]) and baker's yeast-based expression technology using its proprietary *Saccharomyces cerevisiae* strains in a system that is a proven option for high yielding protein production. The company manufactures a range of recombinant proteins for industrial cell culture, bulk drug manufacturing and protein drug formulation.

For further information on Novozymes Biopharma's products and technologies, please visit <http://biopharma.novozymes.com>.

About Novozymes

Novozymes is the world leader in bioinnovation. Together with customers across a broad array of industries we create tomorrow's industrial biosolutions, improving our customers' business and the use of our planet's resources.

With over 700 products used in 130 countries, Novozymes' bioinnovations improve industrial performance and safeguard the world's resources by offering superior and sustainable solutions for tomorrow's ever-changing marketplace.

Novozymes' natural solutions enhance and promote everything from removing trans fats in cooking, to advancing biofuels to power the world tomorrow. Our never-ending exploration of nature's potential is evidenced by over 6,000 patents, showing what is possible when nature and technology join forces.

Our 5,000+ employees working in research, production and sales around the world are committed to shaping business today and our world tomorrow.

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