



News release

Bayer Biological Products Announces Extension of Enhanced Tamper-Evident Packaging Features

Introduction of Shrink-Banding Marks Latest Phase in Bayer BP's Global Initiative to Enhance the Safety of Biological Products

RESEARCH TRIANGLE PARK, N.C. (September 29, 2003) — Bayer Biological Products (BP) announced today it plans to introduce shrink-banding as an enhanced tamper-evident packaging innovation for all liquid products in vials produced at its Clayton, N.C., production facility. The company said it also is actively pursuing alternative packaging safety innovations for other Bayer BP products in a manner responsive to product differences and the unique needs of various geographic regions.

Last year, Bayer BP became the first company in the biological products industry to introduce enhanced packaging safety innovations in response to tampering concerns. Today's announcement marks the latest phase in this product safety initiative, which includes packaging and distribution innovations, patient and treater education, and inter-industry collaboration.

The first product to feature the shrink-band is Gamunex[®], Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified, Bayer BP's next-generation IGIV product recently approved in the United States and Canada.

"It is fitting that Gamunex[®] becomes the first product to feature our latest enhanced tamper-evident

packaging feature," said Dr. Gunnar Riemann, president, Bayer Biological Products Division. "As the first completely new IGIV product development in more than a decade, Gamunex[®] demonstrated its excellent safety profile in the largest clinical trials program ever conducted for licensure of an IGIV. From its innovative production process, all the way through to packaging and distribution, Gamunex[®] offers patients the assurance of Bayer BP's all-encompassing commitment to safety."

The shrink-band is designed as a clear plastic wrap, covering the neck and lid of the bottle with the imprinted Bayer BP logo. The shrink-band comes with a pull-tab for easy removal. If tampering has occurred, the shrink-band will be broken or loosened, and the disruption will be obvious to the naked eye. Additionally, the shrink-band contains the Bayer BP logo, making it difficult to duplicate. If a disruption in packaging is identified, the product should not be opened or used.

"We applaud Bayer BP for taking an important step in enhancing product safety. The new packaging should reduce or eliminate future tampering with Bayer's lifesaving products. This most recent safety step is yet another demonstration of the company's commitment to the patient communities it serves," said Dr. G. Richard Barr, chairman of the Immune Deficiency Foundation.

Although not an issue with Gamunex[®], which will include shrink-banding from the time of launch, inventory of other products may lead to a period of time during which both shrink-banded and non-shrink-banded product is present in the market. Bayer BP will broadly communicate the addition of shrink-banding as each product is introduced with this new feature to ensure a smooth transition, specifically for those products where both product versions are available for some time. Although during the introductory phase there may be product in inventory without shrink-banding, this in no way indicates it is unsafe. Customers, treaters, and patients are encouraged to call Bayer Clinical Communications at 1-800-288-8371 with any questions.

About Bayer HealthCare AG

Bayer HealthCare combines the global activities of the divisions of Bayer AG in the fields of Biological Products, Consumer Care, Diagnostics, Animal Health, and Pharmaceuticals. More than 34,000 employees support the worldwide operations of Bayer HealthCare.

Bayer Biological Products is part of the worldwide operations of Bayer HealthCare, a subgroup of Bayer AG. Bayer HealthCare is one of the world's leading innovators in the health care and medical products industries.

Information about Bayer Biological Products Division can be found at www.bayerbiologicals.com.

Contact:

Tricia McKernan

Tel.: 919.316.6316, Fax: 919.316.6673

E-mail: tricia.mckernan.b@bayer.com

Forward-looking statements

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