

EMERGENT

Emergent BioSolutions Receives NAI Status for Baltimore Bayview Manufacturing Facility

March 25, 2024

GAITHERSBURG, Md., March 25, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) announced that the U.S. Food and Drug Administration (FDA) has listed "No Action Indicated" or NAI status classification for the company's Baltimore Bayview manufacturing facility. Based on this outcome, the Baltimore Bayview facility is considered to be in an acceptable state of compliance with regard to current good manufacturing practices (cGMP).

"Quality and compliance excellence remains a top priority for Emergent and is embedded into our company culture and identity in service of our mission to protect and enhance life," said Coleen Glessner, executive vice president, risk, regulatory, ethics and compliance and chief quality officer. "We are proud of our colleagues who have worked relentlessly to achieve this NAI status in Bayview."

Emergent is committed to ensuring continued compliance with cGMP requirements and remains steadfast in manufacturing and delivering high-quality products for the customers, partners, and patients it serves.

"This news is a result of the commitment and actions our cross-functional teams have taken to strengthen our operational quality and compliance systems across our manufacturing network," said Bill Hartzel, senior vice president, manufacturing and bioservices. "We will continue to put quality and compliance first in our manufacturing operations to ensure we're delivering high quality products to our customers and patients."

The result of obtaining NAI status in Bayview is a continuation of Emergent's strong commitment to quality and compliance. In 2023, Emergent manufacturing facilities were successfully inspected by five regulatory agencies across the globe and five other inspectional bodies for 18 inspections, including three by the FDA that resulted in NAI or VAI status. This includes the closing of the [Baltimore - Camden Warning Letter](#) in 14 months.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For 25 years, we've been at work defending people from things we hope will never happen—so we are prepared just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our [website](#) and follow us on [LinkedIn](#), [X](#), [Instagram](#), [Apple Podcasts](#) and [Spotify](#).

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statements will be accurate. Readers should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers are, therefore, cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statement speaks only as of the date of this press release and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

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Source: Emergent BioSolutions