Athenex Pharmaceutical Division
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Schaumburg, IL 60173

www.AthenexPharma.com

July 1, 2020

Dear Healthcare Professional,

The U.S. Food and Drug Administration (FDA) issued regulatory discretion to temporarily manufacture Rocuronium Bromide Injection with a vial cap (seal) that does not incorporate the "Paralyzing Agent" statement. Supply constraints prevent obtaining the components with the statement on the vial cap. Discretion is approved for product manufactured through July 2020.

Athenex markets **Rocuronium Bromide Injection 50 mg per 5 mL** (NDC 70860-651-05).

The vial cap with the required warning statement and the vial cap without the warning statement are pictured below in Figure 1. This product will have the same container and carton labels as before, which includes a paralyzing agent warning statement on both the vial labels and on the carton. Only the vial caps will change.

Figure 1

Usual Approved Seal

Temporary Approved Seal

The "paralyzing agent" warning statement assists healthcare professionals in clearly identifying neuromuscular blocking agents that produce muscle paralysis (including the muscles associated with breathing), and can cause significant patient harm, including death, when used in error.

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The absence of the "paralyzing agent" warning statement on the vial cap may cause the vial to look like another medication when stored upright in a cabinet drawer or on a shelf next to other drugs. Safe handling of these neuromuscular blocking agents is vital to prevent medication errors that could result in serious harm or death. Please ensure this temporary change in the vial cap is communicated to all relevant staff and consider additional safety measures (i.e., affixing auxiliary 'warning: paralyzing agent' stickers to vial caps) as necessary to minimize the potential for medication errors.

Athenex is committed to helping reduce the risk of medication errors through our proprietary and highly-differentiated AccuraSEE℠ Packaging and Labeling. With a unique AccuraSEE label design for every Athenex product, we're striving to assist healthcare professionals in accurate medication selection.

Should you have any questions regarding this temporary change, adverse events, or product quality concerns, please contact Athenex Medical Affairs at 855-273-0154 or athenexpharma.com/#contact.

FDA MedWatch Adverse Event Reporting Program

The FDA's MedWatch Adverse Event Reporting Program can be accessed online, by regular mail or by fax to report any adverse reactions, medication errors or product quality concerns.

Online:

- Go to **www.fda.gov/medwatch/report.htm**
- Complete and submit the form

Regular Mail or Fax:

- Go to **www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088** to request a reporting form.
- Complete and return to the address on the pre-addressed form
- Or, submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Thank you for your attention to this important matter.

Sincerely,

Sheila Moran
Vice President Quality Assurance