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FDA issues warning to Grand Isle drugmaker

‘Assessment’ requested after violations by APP

By **Samantha Maziarz Christmann**

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APP Pharmaceuticals, a Grand Island drugmaker, has received a warning letter from the Food and Drug Administration.

The letter notified the Staley Road manufacturer that the FDA expects it to “undertake a comprehensive and global assessment” of its operations, particularly its “aseptic processing capabilities.”

The FDA inspected the plant in July, citing several “significant violations,” including insects found in vials of finished product, products with missing labels, a failure to follow quality- control procedures and improper investigating of customer complaints.

The latest letter says APP failed to properly address or correct the violations in its July response to the inspection. A statement from APP’s board of management said that the company has “full confidence” in its products’ quality and that it expects to respond satisfactorily to the FDA’s concerns.

The warning letter also said APP is manufacturing certain prescription drugs without an approved application. APP said the five drugs in question were “grandfathered,” or on the market long enough not to require FDA approval prior to 2006.

“APP has committed to the FDA that it will submit the necessary documentation for approval,” said Matthias Link, an APP spokesman. “Out of the five products, one has already been submitted, there has already been a pre-investigational new drug meeting for another, and documentation for the other three products is currently already under preparation.”

Those generic drugs have annual sales of about $20 million, APP said.

The situation is not expected to affect sales or earnings of German parent company Fresenius Kabi, the firm said.