FDA investigators and Alabama state inspectors observed significant deficiencies that raise concerns about Medistat's ability to assure the sterility of drug products that it produced" FDA (2015).
FDA report "FDA alerted health care professionals and patients of a voluntary recall of all non-expired drug products produced for sterile use and distributed nationwide by Medistat RX, LLC, in Foley, Alabama, due to possible contamination. During an ongoing inspection, FDA investigators and Alabama state inspectors observed significant deficiencies that raise concerns about Medistat's ability to assure the sterility of drug products that it produced. The recalled products were distributed between November 1, 2014, and September 3, 2015."

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