

## FDA Issues First Warning Letter Based on “Serious Violations” of Part 117 CGMP Regulations

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On March 16, 2018, FDA issued a warning letter to Bhavani Fruits and Vegetables LLC in Maspeth, New York for “serious violations” of Current Good Manufacturing Practice (CGMP) requirements under 21 CFR Part 117. We believe this is the first instance in which FDA has formally cited Part 117 CGMP regulations promulgated under FSMA in a warning letter (as opposed to Part 110 CGMP regulations that preceded FSMA).

The date for compliance with the revised CGMP regulations for large businesses (with at least 500 full-time equivalent employees) on was September 19, 2016 and for small businesses (businesses with fewer than 500 full-time equivalent employees) was September 18, 2017. The compliance date for very small businesses (businesses averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale) is September 17, 2018.

For several months, FDA’s Warning Letters have included a footnote noting that the old food CGMP regulations (21 CFR Part 110) had been modernized under Part 117 and that an “establishment will continue to be subject to Part 110 until the Part 117 compliance date applicable to its business size.” FDA continues to use this footnote in warning letters, including a March 21, 2018 [warning letter to Starlight Desserts Inc.](#) (It is not clear whether Starlight Desserts is a very small business not yet subject to mandatory CGMP regulations.) In light of the Bhavani Fruits and Vegetables warning letter, we expect to see more citations to Part 117 CGMP violations in future warning letters.

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