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Comments to Docket No. FDA-2013-D-0984
Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration

November 5, 2013

Dear Sir/Madam:

Novartis has reviewed the above referenced draft guidance and we appreciate the opportunity for comment. We have two questions for clarification that we believe should be addressed in the final guidance:

1. Will the DUNS number be an additional number or a replacement for the existing numbers?
2. If a facility has a CFN or FEI number will they be required to also obtain a DUNS number, and how will the process and timeline for this update be implemented?

Novartis appreciates this opportunity to provide comment.

Sincerely,

Gretchen Trout

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