



Gretchen Trout  
Head North America Policy &  
FDA Liaison

Novartis Pharmaceuticals Corporation  
1700 Rockville Pike  
Suite 510  
Rockville, MD 20852

**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Novartis has reviewed the above referenced draft guidance and we appreciate the opportunity for comment.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*

Gretchen Trout  
Head, North America Policy & FDA Liaison  
US Regulatory and Development Policy  
Drug Regulatory Affairs  
Novartis Pharmaceuticals Corporation