



Kathleen S. Greene
Executive Director
Pharma Dev TRD/QA

Novartis Pharmaceuticals
One Health Plaza
Building 401/A146B
East Hanover, NJ 07936
USA

Tel 862 778 8623
Fax 973 781 5929

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US Food and Drug Administration
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5630 Fishers Lane, Room 1061
Rockville, MD 20852

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Novartis Comments on the Direct final rule *Current Good Manufacturing Practice Regulation and Investigational New Drugs*

Dear Sir/Madam,

The Quality Assurance group from Technical R&D of Novartis Pharmaceuticals is pleased to provide these comments on the Direct final rule *Current Good Manufacturing Practice Regulation and Investigational New Drugs*.

1. When the proposed rule is made final, it is implied that all portions of 210 and 211 could be considered applicable to phases 2 and 3. This would place undue burden on the industry since all parts of 21 CFR Parts 210 and 211, as written, are not appropriate for phase 2 and 3. Therefore, we suggest:
 - that it be made clear that incremental application of CGMP is expected for production and testing of Phase 2 and 3 clinical supplies
 - or
 - that the 1991 FDA Guideline for the Preparation of Investigational New Drug Products remain in effect for phase 2 and 3 materials until the new phase 2 and 3 guidance document is available.
2. It should be made clear that the direct final rule applies to investigational new drug products, and not to APIs.

We appreciate the opportunity to comment on this Direct final rule. Please contact us if we can be of any further assistance.

Sincerely,

Kathleen Greene

Executive Director Technical R&D QA US
Novartis Pharmaceuticals