



Pharmaceuticals

December 20, 2006

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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Dear Sirs and Madams:

Re: **Docket No. 2006D-0344**
Draft Guidance for Industry: Drug Interaction Studies
Study Design, Data Analysis, and Implications for Dosing and Labeling

Ladies and Gentlemen:

Reference is made to the Federal Register Notice dated September 12, 2006 (Docket No. 2006D-0344) requesting comments on the guidance for industry entitled "Guidance for Industry: Drug Interaction Studies Study Design, Data Analysis, and Implications for Dosing and Labeling".

In accordance with the above mentioned Federal Register Notice, Hoffmann La Roche, Inc. (Roche) is herewith providing input/recommendations on the above mentioned Draft Guidance, see attached document. By way of background, Roche is a research based pharmaceutical company with extensive experience in designing and conducting preclinical and clinical pharmacology programs to support the development and regulatory approval of drugs and biologics. Roche development programs have included in vitro and in vivo drug metabolism, drug transport and drug-drug interaction studies, studies which are specifically addressed in the draft guidance. As a company, Roche has a significant interest in and recognizes the importance of the provisions addressed in the Draft Guidance and welcomes the opportunity to comment on the guidance.

The comments included herein were provided by a Roche global DDI working group with extensive experience and interest in this scientific discipline and we hope the Agency will consider the comments and recommendations provided. The attached document provides general comments as well as specific comments sections of the draft guidance for your consideration.

We would like to thank the Agency for the efforts that have been put into developing this draft guidance and for the opportunity to provide comment. Roche would be happy to clarify any points included in the attached communication.

Yours sincerely,

HOFFMANN-LA ROCHE INC.

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Attachments
HLR No. N2006-03627

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