Guidance for Industry

Drug Interaction Studies — Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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TABLE OF CONTENTS

LIST OF FIGURES **2**

LIST OF TABLES **2**

I. INTRODUCTION **1**

II. SUMMARY OF GUIDANCE **2**

III. BACKGROUND **6**

A. Relevance of Drug Interactions 6
B. Drug Interaction Considerations for Small Molecule Drugs 7
C. Drug Interaction Considerations for Therapeutic Proteins 14

IV. GENERAL STRATEGIES **14**

A. In Vitro Studies 15
B. In Vivo Studies 33
1. In Vivo Drug-Drug Interactions 33
2. In Vivo Drug-Therapeutic Protein (TP) Interactions 33
C. Using a Population Pharmacokinetic Approach to Assess Drug-Drug Interactions 36

V. DESIGN OF IN VIVO DRUG-DRUG INTERACTION STUDIES **36**

A. Study Design 36
B. Study Population 39
C. Choice of Substrate and Interacting Drugs 39
D. Route of Administration 55
E. Dose Selection 55
F. Endpoints 56
G. Statistical Considerations and Sample Size 57

VI. LABELING RECOMMENDATIONS **58**

A. Drug Interactions Section of Labeling 59
B. Clinical Pharmacology Section of Labeling 60
C. Other Labeling Sections 62

LIST OF FIGURES IN THE APPENDIX **63**

APPENDIX **64**

REFERENCES **71**

ABBREVIATIONS **75**

List of Figures

Figure 1. Illustration of Examples of Efflux and Uptake Transporters in the Gut Wall (A), Liver (B), and Kidneys (C) that May Be Involved in a Drug's Absorption, Distribution, Metabolism, and Excretion. 9
Figure 2. Metabolism-Based Drug-Drug Interaction Studies — Decision Tree 16
Figure 3. Evaluation of Investigational Drugs as UGT Substrates 20
Figure 4. General Scheme of Model-Based Prediction: The Investigational Drug (and Metabolite Present at ≥25% of Parent AUC) as an Interacting Drug of CYP Enzymes 23
Figure 5. Using a PBPK Model to Explore Drug-Drug Interaction Potential Between a Substrate Drug and an Interacting Drug. 29
Figure 6. Evaluation of Investigational Drugs as Substrates for P-gp, BCRP, OATP1B1, OATP1B3, OAT1, OAT3, and OCT2 Transporters. 31
Figure 7. Summary of The Types of Studies That Have Been Used During Drug Development to Evaluate Therapeutic Protein (TP)–Small-Molecule Drug (D) Interactions. 35
Figure 8. The Effect of Various CYP Inhibitors on a Hyperthetical Drug's PK as Displayed as 90% Confidence Interval of Geometric Mean AUC and C_{max} Ratios. 61

List of Tables

Table 1. Selected Transporter-Mediated Clinical Significant Drug-Drug Interactions 12
Table 2. In Vitro CYP Inducers 27
Table 3. Classification of In Vivo Inhibitors of CYP Enzymes 41
Table 4. Classification of In Vivo Inducers of CYP Enzymes 43
Table 5. Examples of Sensitive In Vivo CYP Substrates and CYP Substrates with Narrow Therapeutic Range 44
Table 6. Examples of In Vivo Inhibitors and Inducers of Selected Transporters 49
Table 7. Examples of In Vivo Substrates of Selected Transporters 51
Table 8. Examples of In Vivo CYP3A and P-gp Inhibitors and Their Relative Potency 53

Guidance for Industry[1]

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I. INTRODUCTION

This guidance provides recommendations for sponsors of new drug applications (NDAs) and biologics license applications (BLAs) for therapeutic biologics regulated by CDER regarding *in vitro* and *in vivo* studies of drug metabolism, drug transport, and drug-drug or drug-therapeutic protein interactions. Drug interactions can result when one drug alters the pharmacokinetics of another drug or its metabolites. Drug interactions also can reflect the additive nature of the pharmacodynamic effect of either drug when taken with the other drug. The main focus of this guidance is pharmacokinetic drug interactions. This guidance reflects the Agency's view that the pharmacokinetic interactions between an investigational new drug and other drugs should be defined during drug development, as part of an adequate assessment of the drug's safety and effectiveness. It is important to understand the nature and magnitude of drug-drug interactions (DDI) for several reasons. Concomitant medications, dietary supplements, and some foods, such as grapefruit juice, may alter metabolism and/or drug transport abruptly in individuals who previously had been receiving and tolerating a particular dose of a drug. Such an abrupt alteration in metabolism or transport can change the known safety and efficacy of a drug.

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[1] This guidance has been prepared by the Drug-Drug Interaction Working Group in the Office of Clinical Pharmacology, Office of Translational Sciences, in the Center for Drug Evaluation and Research (CDER), with input from other offices in CDER.

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