

Final Rule on Prescription Drug Labeling January 24, 2006

§201.57: Specific Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (pg 3988-3996)

Highlights of Prescribing Information.....	201.57(a)
Highlights limitation statement	201.57(a)(1)
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4 Contraindications.....	201.57(c)(5)
5 Warnings and Precautions.....	201.57(cX6)
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8 Use in Specific Populations	201.57(c)(9)
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9 Drug Abuse and Dependence.....	201.57(cX10)
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13 Nonclinical Toxicology	201.57(c)(14)
13.1 Carcinogenesis, mutagenesis, impairment of fertility	
13.2 Animal toxicology and/or pharmacology	
14 Clinical Studies	201.57(c)(15)
15 References	201.5700(16)
16How Supplied/Storage and Handling.....	201.57(c)(17)
17 Patient Counseling Information	201.57(c)(18)

Reorganizing Labeling Sections

Location in Old Format		Location in FPI in New Format
Boxed Warning	⇒	Boxed Warning
Description	⇒	11 Description
Clinical Pharmacology	⇒	12 Clinical Pharmacology
Indications and Usage	⇒	1 Indications and Usage
Contraindications	⇒	4 Contraindications
Warnings	⇒	5 Warnings and Precautions
Precautions		
General	⇒	5 Warnings and Precautions
Information for Patients	⇒	17 Patient Counseling Information
Laboratory Tests	⇒	5 Warnings and Precautions
Drug Interactions	⇒	7 Drug Interactions
Drug/Laboratory Test Interactions	⇒	5 Warnings and Precautions
Carcinogenesis, Mutagenesis, Impairment of Fertility	⇒	13.1 Nonclinical Toxicology (Carcinogenesis, Mutagenesis, Impairment of Fertility)
Pregnancy	⇒	8.1 Use in Specific Populations (Pregnancy)
Labor and Delivery	⇒	8.2 Use in Specific Populations (Labor and Delivery)
Nursing Mothers	⇒	8.3 Use in Specific Populations (Nursing Mothers)
Pediatric Use	⇒	8.4 Use in Specific Populations (Pediatric Use)
Geriatric Use	⇒	8.5 Use in Specific Populations (Geriatric Use)
Adverse Reactions	⇒	6 Adverse Reactions
Drug Abuse and Dependence	⇒	9 Drug Abuse and Dependence
Overdosage	⇒	10 Overdosage
Dosage and Administration	⇒	2 Dosage and Administration
How Supplied	⇒	3 Dosage Forms and Strengths 16 How Supplied/Storage and Handling
Animal Pharmacology and/or Animal Toxicology	⇒	13.2 Nonclinical Toxicology (Animal Toxicology and/or Pharmacology)
Clinical Studies	⇒	14 Clinical Studies
References	⇒	15 References