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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 201--LABELING--Table of Contents

Subpart B--Labeling Requirements for Prescription Drugs and/or Insulin

Sec. 201.56 General requirements on content and format of labeling for human prescription drugs.

Prescription drug labeling described in Sec. 201.100(d) shall contain the information in the format required by Sec. 201.57 and shall meet the following general requirements:

- (a) The labeling shall contain a summary of the essential scientific information needed for the safe and effective use of the drug.
- (b) The labeling shall be informative and accurate and neither promotional in tone nor false or misleading in any particular.
- (c) The labeling shall be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling, headings for which are listed in paragraph (d) of this section.
- (d)(1) The labeling shall contain specific information required under Sec. 201.57 under the following section headings and in the following order:

Description.

Clinical Pharmacology.

Indications and Usage.

Contraindications.

Warnings.

Precautions.

Adverse Reactions.
Drug Abuse and Dependence.
Overdosage.
Dosage and Administration.
How Supplied.

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with Sec. 201.57 (l) and (m):

Animal Pharmacology and/or Animal Toxicology.
Clinical Studies.
References.

(3) The labeling may omit any section or subsection of the labeling format if clearly inapplicable.

(4) The labeling may contain a "Product Title" section preceding the "Description" section and containing only the information required by Sec. 201.57(a)(1)(i), (ii), (iii), and (iv) and Sec. 201.100(e). The information required by Sec. 201.57(a)(1)(i), (ii), (iii), and (iv) shall appear in the "Description" section of the labeling, whether or not it also appears in a "Product Title."

(e) The labeling shall contain the date of the most recent revision of the labeling, identified as such, placed

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prominently immediately after the last section of the labeling.

[44 FR 37462, June 26, 1979]