§ 201.55 Statement of dosage.

Section 201.100(b)(2) requires that labels for prescription drugs bear a statement of the recommended or usual dosage. Since the dosage for some prescription drugs varies within extremely wide limits, depending upon the conditions being treated, it may not be possible in all cases to present an informative or useful statement of the recommended or usual dosage in the space available on the label or carton of the package. It is the view of the Food and Drug Administration that when such a situation prevails, compliance with this requirement would be met by a statement such as “See package insert for dosage information”, where the detailed information is contained in such insert. However, if an informative, realistic, recommended or usual dosage can readily be set forth on the label, it should appear thereon.

§ 201.56 Requirements on content and format of labeling for human prescription drug and biological products.

(a) General requirements. Prescription drug labeling described in § 201.100(d) must meet the following general requirements:

(1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(2) The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. In accordance with §§314.70 and 601.12 of this chapter, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading.

(3) The labeling must 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 must be identified as such and included with human data in the appropriate section of the labeling.

(b) Categories of prescription drugs subject to the labeling content and format requirements in §§201.56(d) and 201.57. (1) The following categories of prescription drug products are subject to the labeling requirements in paragraph (d) of this section and §201.57 in accordance with the implementation schedule in paragraph (c) of this section:

(i) Prescription drug products for which a new drug application (NDA), biologics license application (BLA), or efficacy supplement was approved by the Food and Drug Administration (FDA) between June 30, 2001 and June 30, 2006;

(ii) Prescription drug products for which an NDA, BLA, or efficacy supplement was pending on June 30, 2006;

(iii) Prescription drug products for which an NDA, BLA, or efficacy supplement is submitted anytime on or after June 30, 2006;
(2) Prescription drug products not described in paragraph (b)(1) of this section are subject to the labeling requirements in paragraph (e) of this section and §201.80.

(c) Schedule for implementing the labeling content and format requirements in §§201.56(d) and 201.57. For products described in paragraph (b)(1) of this section, labeling conforming to the requirements in paragraph (d) of this section and §201.57 must be submitted according to the following schedule:

(1) For products for which an NDA, BLA, or efficacy supplement is submitted for approval on or after June 30, 2006, proposed conforming labeling must be submitted as part of the application.

(2) For products for which an NDA, BLA, or efficacy supplement is pending on June 30, 2006, or that has been approved any time from June 30, 2005, up to and including June 30, 2006, a supplement with proposed conforming labeling must be submitted no later than June 30, 2009.

(3) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2004, up to and including June 29, 2005, a supplement with proposed conforming labeling must be submitted no later than June 30, 2010.

(4) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2003, up to and including June 29, 2004, a supplement with proposed conforming labeling must be submitted no later than June 30, 2011.

(5) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2002, up to and including June 29, 2003, a supplement with proposed conforming labeling must be submitted no later than June 30, 2012.

(6) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2001, up to and including June 29, 2002, a supplement with proposed conforming labeling must be submitted no later than June 30, 2013.

(d) Labeling requirements for new and more recently approved prescription drug products. This paragraph applies only to prescription drug products described in paragraph (b)(1) of this section and must be implemented according to the schedule specified in paragraph (c) of this section.

(1) Prescription drug labeling described in §201.100(d) must contain the specific information required under §201.57(a), (b), and (c) under the following headings and subheadings and in the following order:

Highlights of Prescribing Information

Product Names, Other Required Information

Boxed Warning

Recent Major Changes

Indications and Usage

Dosage and Administration

Dosage Forms and Strengths

Contraindications

Warnings and Precautions

Adverse Reactions

Drug Interactions

Use in Specific Populations

Full Prescribing Information: Contents

Full Prescribing Information

Boxed Warning

1 Indications and Usage

2 Dosage and Administration

3 Dosage Forms and Strengths

4 Contraindications

5 Warnings and Precautions

6 Adverse Reactions

7 Drug Interactions

8 Use in Specific Populations

8.1 Pregnancy

8.2 Labor and delivery

8.3 Nursing mothers

8.4 Pediatric use

8.5 Geriatric use

9 Drug Abuse and Dependence

9.1 Controlled substance

9.2 Abuse

9.3 Dependence

10 Overdosage

11 Description

12 Clinical Pharmacology

12.1 Mechanism of action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 Nonclinical Toxicology

13.1 Carcinogenesis, mutagenesis, impairment of fertility

13.2 Animal toxicology and/or pharmacology

14 Clinical Studies

15 References

16 How Supplied/Storage and Handling

17 Patient Counseling Information
(2) Additional nonstandard subheadings that are used to enhance labeling organization, presentation, or ease of use (e.g., for individual warnings or precautions, or for each drug interaction) must be assigned a decimal number that corresponds to their placement in labeling. The decimal numbers must be consistent with the standardized identifying numbers listed in paragraph (d)(1) of this section (e.g., subheadings added to the "Warnings and Precautions" section must be numbered 5.1, 5.2, and so on).

(3) Any reference in Highlights to information appearing in the full prescribing information must be accompanied by the identifying number (in parentheses) corresponding to the location of the information in the full prescribing information.

(4) Omit clearly inapplicable sections, subsections, or specific information. If sections or subsections required under paragraph (d)(1) of this section are omitted from the full prescribing information, the heading “Full Prescribing Information: Contents” must be followed by an asterisk and the following statement must appear at the end of Contents: “* Sections or subsections omitted from the full prescribing information are not listed.”

(5) Any risk information that is required under §201.57(c)(9)(iv) is considered “appropriate pediatric contraindications, warnings, or precautions” within the meaning of section 565A(1)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355A(1)(2)), whether such information appears in the “Contraindications,” “Warnings and Precautions,” or “Use in Specific Populations” section of labeling.

(e) Labeling requirements for older prescription drug products. This paragraph applies only to approved prescription drug products not described in paragraph (b)(1) of this section.

(1) Prescription drug labeling described in §201.100(d) must contain the specific information required under §201.80 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 §201.80(l) and (m):
   Animal Pharmacology and/or Animal Toxicology
   Clinical Studies
   References

(3) Omit clearly inapplicable sections, subsections, or specific information.

(4) The labeling may contain a “Product Title” section preceding the “Description” section and containing only the information required by §201.80(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(1)(iv) and §201.100(e). The information required by §201.80(a)(1)(i) through (a)(1)(iv) must appear in the “Description” section of the labeling, whether or not it also appears in a “Product Title.”

(5) The labeling must contain the date of the most recent revision of the labeling, identified as such, placed prominently immediately after the last section of the labeling.

(6) The requirement in §201.80(f)(2) to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling must be implemented no later than June 30, 2007.

[71 FR 3986, Jan. 24, 2006]