



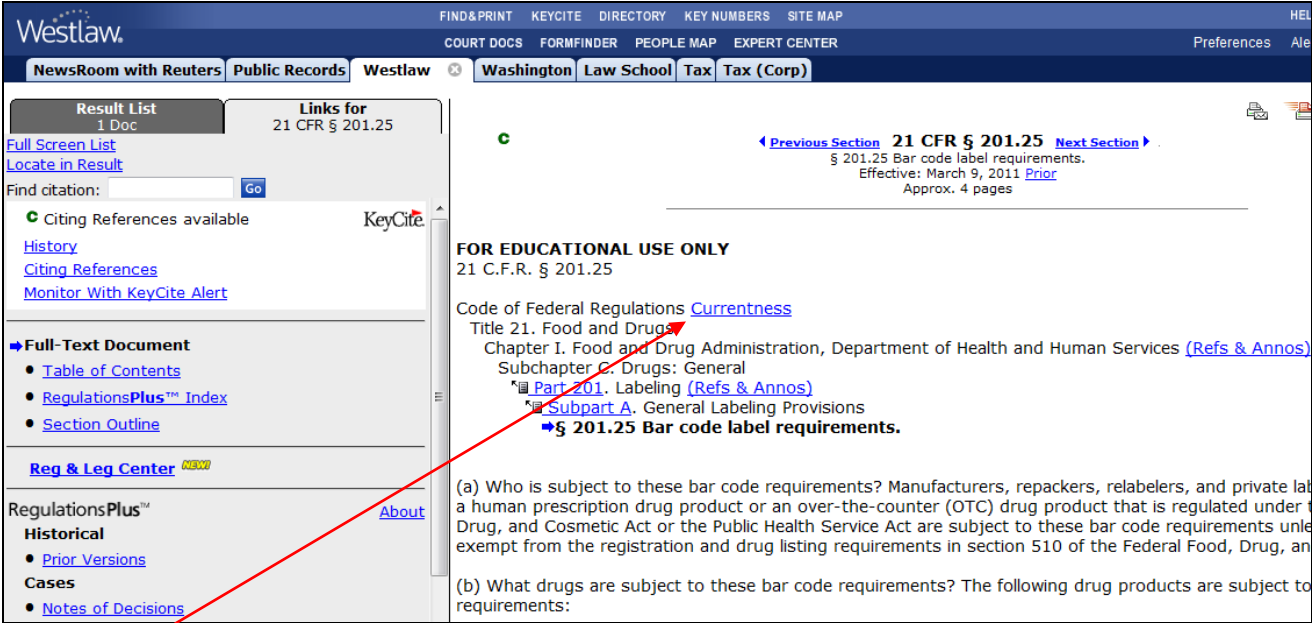
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Research Guide

Listed below are the steps in updating a federal regulation to determine if it has been amended, repealed or superseded. For this example, we will update 21 C.F.R. § 201.25.

- Updating 21 C.F.R. § 201.25 on Classic Westlaw.



- After you retrieve a *CFR* citation, click the *Currentness* link at the top of the screen.

[◀ Previous Section](#) **21 CFR § 201.25** [Next Section ▶](#)
 § 201.25 Bar code label requirements.
 Effective: March 9, 2011 [Prior](#)
 Approx. 4 pages

(1) On our own initiative, or in response to a written request from a manufacturer, repacker, relabeler or private label distributor, we may exempt a drug product from the bar code label requirements set forth in this section. The exemption request must document why:

(i) compliance with the bar code requirement would adversely affect the safety, effectiveness, purity or potency of the drug or not be technologically feasible, and the concerns underlying the request could not reasonably be addressed by measures such as package redesign or use of overwraps; or

(ii) an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.

(2) Requests for an exemption should be sent to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002 (requests involving a drug product) or to the Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 (requests involving a biological product).

[[69 FR 9170](#), Feb. 26, 2004; [76 FR 12847](#), March 9, 2011]

SOURCE: [40 FR 13998](#), March 27, 1975; [51 FR 8182](#), March 7, 1986; [51 FR 43904](#), Dec. 5, 1986; [52 FR 2111](#), Jan. 20, 1987; [53 FR 4135](#), Feb. 12, 1988; [54 FR 39635](#), Sept. 27, 1989; [57 FR 54300](#), Nov. 18, 1992; [58 FR 45201](#), Aug. 26, 1993; [62 FR 51515](#), Oct. 1, 1997; [63 FR 26698](#), May 13, 1998; [64 FR 400](#), Jan. 5, 1999, unless otherwise noted.

AUTHORITY: [21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e](#); [42 U.S.C. 216, 241, 262, 264](#).

[NOTES OF DECISIONS](#)

21 C. F. R. § 201.25, 21 CFR § 201.25
 Current through March 10, 2011; 76 FR 13099

- Note that the *CFR* database on Classic Westlaw is current through the March 10, 2011 issue of the *Federal Register* (76 FR 13,099).
- Note that Classic Westlaw provides a *Source Note* and *Authority Note* for every section of the *CFR*.
- Note that the latest amendment to 21 C.F.R. § 201.25 was on March 9, 2011 and that was in Volume 76 of the *Federal Register* on page 12,847 (76 FR 12, 847).

- Updating 21 C.F.R. § 201.25 on WestlawNext

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§ 201.25 Bar code label requirements.
Code of Federal Regulations | Title 21, Food and Drugs | Effective: March 9, 2011

Document | Notes of Decisions (2) | History (3) | Citing References (39) | Context & Analysis (14) | Powered by KeyCite

Code of Federal Regulations
Title 21, Food and Drugs
Chapter I, Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter C, Drugs: General
Part 201, Labeling (Refs & Annos)
Subpart A, General Labeling Provisions

21 C.F.R. § 201.25

§ 201.25 Bar code label requirements.

[Currentness](#)

(a) Who is subject to these bar code requirements? Manufacturers, repackers, relabelers, and private label distributors of a human prescription drug product or an over-the-counter (OTC) drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to these bar code requirements unless they are exempt from the registration and drug listing requirements in section 510 of the Federal Food, Drug, and Cosmetic Act.

(b) What drugs are subject to these bar code requirements? The following drug products are subject to the bar code label requirements:

- Note the *Currentness* link.

Credits

[69 FR 9170, Feb. 26, 2004; 76 FR 12847, March 9, 2011]

SOURCE: 40 FR 13998, March 27, 1975; 51 FR 8182, March 7, 1986; 51 FR 43904, Dec. 5, 1986; 52 FR 2111, Jan. 20, 1987; 53 FR 4135, Feb. 12, 1988; 54 FR 39635, Sept. 27, 1989; 57 FR 54300, Nov. 18, 1992; 58 FR 45201, Aug. 26, 1993; 62 FR 51515, Oct. 1, 1997; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

Notes of Decisions (2)

Current through March 10, 2011; 76 FR 13099

- Just like Classic Westlaw – WestlawNext provides the *Source Note* and *Authority Note*.
- WestlawNext also indicates that 21 C.F.R. § 201.25 was last amended on March 9, 2011 and that was in Volume 76 of the *Federal Register* on page 12,847 (76 FR 12, 847).

- Updating 21 C.F.R. § 201.25 on LexisNexis.

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Citation: 21 C.F.R. 201.25

21 CFR 201.25

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*** THIS SECTION IS CURRENT THROUGH THE MARCH 17, 2011 ***
*** ISSUE OF THE FEDERAL REGISTER ***

TITLE 21 -- FOOD AND DRUGS
CHAPTER I -- FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C -- DRUGS: GENERAL
PART 201 -- LABELING
SUBPART A -- GENERAL LABELING PROVISIONS

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21 CFR 201.25

♦ 201.25 Bar code label requirements.

(a) Who is subject to these bar code requirements? Manufacturers, repackers, relabelers, and private label distributors of a human prescription drug product (OTC) drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to these bar code requirements, except those exempt from the registration and drug listing requirements in section 510 of the Federal Food, Drug, and Cosmetic Act.

(b) What drugs are subject to these bar code requirements? The following drug products are subject to the bar code label requirements:

- Note that the *CFR* source on LexisNexis is current through the March 17, 2011 issue of the *Federal Register*.

(2) Requests for an exemption should be sent to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 51, Silver Spring, MD 20993-0002 (requests involving a drug product) or to the Office of Compliance and Biologics Quality (HFM), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 (requests involving a biological product).

HISTORY:

[69 FR 9120, 9170, Feb. 26, 2004; 76 FR 12847, Mar. 9, 2011]

AUTHORITY:

AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

- Note that the latest amendment to 21 C.F.R. § 201.25 was on March 9, 2011 and that was in Volume 76 of the *Federal Register* on page 12,847.

- Updating 21 C.F.R. § 201.25 using e-CFR on GPO Access - <http://ecfr.gpoaccess.gov>

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Title 21: Food and Drugs
[PART 201—LABELING](#)
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§ 201.25 Bar code label requirements.

(a) *Who is subject to these bar code requirements?* Manufacturers, repackers, relabelers, and private label distributors of a human prescription drug product or an over-the-counter (OTC) drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to these bar code requirements unless they are exempt from the registration and drug listing requirements in section 510 of the Federal Food, Drug, and Cosmetic Act.

(b) *What drugs are subject to these bar code requirements?* The following drug products are subject to the bar code label requirements:

(1) Prescription drug products, however:

(i) The bar code requirement does not apply to the following entities:

(A) Prescription drug samples;

(B) Allergenic extracts;

for patient safety.

(2) Requests for an exemption should be sent to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002 (requests involving a drug product) or to the Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 (requests involving a biological product).

[69 FR 9170, Feb. 26, 2004, as amended at 76 FR 12847, Mar. 9, 2011]

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- The e-CFR states that it is current to March 23, 2011. In the source note for 21 C.F.R. § 201.25 it does reflect that it was amended on March 9, 2011 by page 12,847 of the *Federal Register*.