

**List of Subjects****21 CFR Part 201**

Drugs, Labeling, Reporting and recordkeeping requirements.

**21 CFR Part 801**

Labeling, Medical devices, Reporting and recordkeeping requirements.

**21 CFR Part 1100**

Combination products, Devices, Drugs, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter 1 is amended as follows:

**PART 201—LABELING**

- 1. The authority citation for part 201 continues to read as follows:

**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.

- 2. Revise § 201.128 to read as follows:

**§ 201.128 Meaning of “intended uses”.**

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. And if the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved (if any), he is required, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly

promulgated regulations exempting the drug from the requirements of section 502(f)(1), to provide for such drug adequate labeling that accords with such other intended uses.

**PART 801—LABELING**

- 3. The authority citation for part 801 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 360d, 360i, 360j, 371, 374.

- 4. Revise § 801.4 to read as follows:

**§ 801.4 Meaning of intended uses.**

The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the device, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. And if the totality of the evidence establishes that a manufacturer objectively intends that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (if any), he is required, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly promulgated regulations exempting the device from the requirements of section 502(f)(1), to provide for such device adequate labeling that accords with such other intended uses.

**PART 1100—TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY**

- 5. The authority citation for part 1100 is revised to read as follows:

**Authority:** 21 U.S.C. 387a(b), 387f(d); Secs. 901(b) and 906(d), Pub. L. 111–31; 21 CFR 16.1 and 1107.1; 21 CFR 1.1, 1.20, 14.55, 17.1, and 17.2. Section 1100.5 is issued under 21 U.S.C. 321, 353(g), and 371(a); 21 CFR 1.1.

- 6. Part 1100 is amended by adding § 1100.5 to read as follows:

**§ 1100.5 Exclusion from tobacco regulation.**

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

(a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction (e.g., smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms;

(b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

Dated: December 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 888**

[Docket No. FDA–2014–N–1205]

**Orthopedic Devices; Reclassification of Pedicle Screw Systems, Henceforth To Be Known as Thoracolumbosacral Pedicle Screw Systems, Including Semi-Rigid Systems****Correction**

In rule document 2016–31670 beginning on page 96366 in the issue of Friday, December 30, 2016, make the following correction:

On page 96372, in the second column, in the 25th, 51st, and 67th lines, and in the third column, in the tenth line, “June 28, 2018” should read “July 1, 2019”.

[FR Doc. C1–2016–31670 Filed 1–6–17; 8:45 am]

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