■
26. **Amend** § 820.120 by *revising the first sentence of paragraph (b)* to read as follows:

§ 820.120 **Device labeling**.
* * * * *
(b) *Labeling inspection*.
Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or universal product code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.
***
* * * * *

■
27. **Amend** § 820.184 *by revising paragraph (f)* to read as follows:

§ 820.184 **Device history record**.
* * * * *
(f) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

■
28. **Amend** § 820.198 by *revising paragraph (e)(3)* to read as follows:

§ 820.198 **Complaint files**.
* * * * *
(e) * * *
(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
* * * * *

■
29. **Amend** § 820.200 *by revising paragraph (d)(2)* to read as follows:

§ 820.200 **Servicing**.
* * * * *
(d) * * *
(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

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REVISIONS to 21 CFR PART 820

Listed below are the revisions made to 21 CFR PART 820—QUALITY SYSTEM REGULATION as amended at 78 FR 55822, Sept. 24, 2013, Unique Device Identification System, Final Rule that are not found printed in this reference. *Besides the addition of the UDI System requirements, the quality system regulation has not changed.* For more information regarding the Unique Device Identification System rule please see our webpage ***http://www.fdaconsulting.com/udi.html*** .
Please call with any questions.

■
24. The authority citation for 21 CFR part 820 continues to read as follows:
Authority:
21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

■
25. **Amend** § 820.3 by *adding new paragraphs* (bb), (cc), and (dd) to read as follows:

§ 820.3 **Definitions**.
* * * * *
(bb) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(cc) *Unique device identifier* (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:

(1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
(2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
(i) The lot or batch within which a device was manufactured;
(ii) The serial number of a specific device;
(iii) The expiration date of a specific device;
(iv) The date a specific device was manufactured.
(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

(dd) *Universal product code* (UPC) means the product identifier used to identify an item sold at retail in the United States.

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UDI Revision Sheet for Noblitt & Rueland QSR Pocket Reference Booklet

Print, cut out and fold on dotted line. Reverse side can be used for any notes.