class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:


products

counter (OTC) for certain uses

certain active ingredients offered over-the-

§ 310.545 Drug products containing (d)(11) to read as follows:

(a)(24)(i) headings, by adding (a)(23) and (a)(24) as paragraphs redesignating the text of paragraphs (a)(23)(ii) and (a)(24)(ii), respectively; by adding paragraphs (a)(23)(ii) and (a)(24)(ii) headings, by adding paragraphs (a)(23)(ii), (a)(24)(ii), and (d)(26); and by revising paragraph (d)(11) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(23) Internal analgesic drug products—(i) Approved as of November 10, 1993. * * *

(ii) Approved as of February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

(24) Orally administered menstrual drug products—(i) Approved as of November 10, 1993. * * *

(ii) Approved as of February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

* * * * * *

(d) * * *

(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric subsulfate) through (a)(18)(vi), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

* * * * * *

(26) February 22, 1999, for products subject to paragraphs (a)(23)(i) and (a)(24)(ii) of this section.


William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 98–22568 Filed 8–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 96N–0320]

Radiology Devices; Classifications for Five Medical Image Management Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of April 29, 1998 (63 FR 23385). The document classified, along with other devices, the medical image storage device and medical image communications device as Class I devices in this rule. However, under § 820.30(a)(2)(i), devices automated with computer software are specifically identified as devices which are subject to design controls. Because the medical image storage device and medical image communications device described by the classification regulation are digital, they are by definition, “automated with computer software.” The agency is therefore clarifying that these devices are subject to design controls.

In FR Doc. 98–11317 appearing on page 23385 in the Federal Register of April 29, 1998, the following corrections are made:

§ 892.10 [Corrected]

1. On page 23387, in the first column, in § 892.10 Medical image storage device, paragraph (a) is corrected by removing the phrase “without irreversible data compression” and paragraph (b) is corrected by adding the phrase “* * * the device transfers images without performing irreversible data compression” at the end of the paragraph.

§ 892.20 [Corrected]

2. On the same page, in the same column, in § 892.20 Medical image communications device, paragraph (a) is corrected by removing the phrase “* * * the device transfers images without performing irreversible data compression” and paragraph (b) is corrected by adding the phrase “* * * only when the device stores images without performing irreversible data compression” at the end of the paragraph.


D.B. Burlington,
Director, Center for Devices and Radiological Health.

[FR Doc. 98–22571 Filed 8–21–98; 8:45 am]

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