Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 2007N–0264]

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Companion Document to Direct Final Rule; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration is correcting a proposed rule that appeared in the **Federal Register** of August 16, 2007 (72 FR 45993). That document proposed to amend the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. The proposal published as a companion document to the direct final rule that published in the same issue of the **Federal Register** (August 16, 2007, 72 FR 45883). Both documents published with a typographical error in the codified section. This document corrects the error in the proposed rule. Elsewhere in this issue of the **Federal Register** we are correcting the error in the direct final rule.

DATES: Submit written or electronic comments on the proposed rule by October 30, 2007.

ADDRESSES: You may submit comments on the proposed rule, identified by Docket No. 2007N–0264, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of the proposed rule (72 FR 45993 at 45995).

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For information regarding this correction*: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

For information regarding the proposed rule: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–15942, appearing on page 45993, in the **Federal Register** of Thursday, August 16, 2007, the following correction is made:

§ 610.53 [Corrected]

1. On page 45996, in the amendment to § 610.53 *Dating periods for licensed biological products*, in the table in paragraph (c), ''65° C'' is corrected to read ''−65° C'' everywhere it appears.

Dated: September 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18802 Filed 9–21–07; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–308P]

Technical Amendment to Listing in Schedule III of Approved Drug Products Containing Tetrahydrocannabinols

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Under the current schedules of controlled substances in the DEA regulations, among the substances listed in schedule III is a synthetic isomer of tetrahydrocannabinols (THC) contained in a specific formulation of a drug product approved by the U.S. Food and Drug Administration (FDA). As currently written, the DEA regulation would not necessarily include drug products approved by the FDA under section 505(j) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355) (commonly referred to as generic drugs) that cite the drug product currently listed in schedule III as the reference listed drug. DEA is hereby proposing to modify the regulation so that certain generic drug products are also included in the schedule III listing.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before November 23, 2007.