4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0838]

Compliance Policy Guide Sec. 253.100--Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled "Sec. 253.100--Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed," issued October 1, 1980, and revised in March 1995.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Medical Products and Tobacco Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled "Sec. 253.100--Use of Units of Plasma and Fresh Frozen Plasma Which Have Been Thawed" on October 1, 1980, and revised it in March 1995. FDA originally issued CPG Sec. 253.100 to provide FDA's current thinking regarding the time limits for when thawed frozen plasma should be used for transfusion. At the time of issuance of the CPG, 21 CFR 606.122(m)(3) provided that the instruction circular shall include, when applicable, instructions to begin administration of the product within 6 hours

after thawing. The CPG noted a planned regulatory change that would allow greater flexibility in the time of administration requirements for frozen plasma products.

In a final rule published in the Federal Register on January 3, 2012 (77 FR 7), with an effective date of July 2, 2012, FDA modified the time limits contained in the instruction circular for when administration of thawed frozen plasma products begins, as required by 21 CFR 606.122(m)(3), to "within a specified time after thawing." As noted in the preamble to the final rule, the change was made "to provide industry with increased flexibility for developing and specifying timeframes for which thawed plasma components can still be used for transfusion if stored at appropriate temperatures per industry standards." (See 77 FR 7 at 14). With this regulatory change, CPG Sec. 253.100 is obsolete.

FDA is therefore withdrawing CPG 253.100, in its entirety, to eliminate the obsolete compliance policy.

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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