DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled “Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)” dated July 2007.

DATES: August 17, 2011.


SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 26, 2007 (72 FR 41080), FDA announced the availability of a draft guidance entitled “Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs).”

FDA has carefully considered the comments received on the draft guidance and, since that document issued in 2007, has gained additional experience with point of care devices and the autologous cells selected by them. Based on these comments and experience, FDA believes that the draft guidance would not, if finalized in current form, reflect FDA’s current thinking. For these reasons, FDA is withdrawing the draft guidance entitled “Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs).”

Dated: August 10, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0246]

Guidance for Industry on Residual Drug in Transdermal and Related Drug Delivery Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Residual Drug in Transdermal and Related Drug Delivery Systems.” This guidance provides recommendations to developers and manufacturers of transdermal drug delivery systems (TDDS), transmucosal drug delivery systems (TMDS), and topical patch products regarding use of an appropriate scientific approach during product design and development—as well as during manufacturing and product life-cycle management—to ensure that the amount of residual drug substance at the end of the labeled use period is minimized.

The guidance is applicable to investigational new drug applications, new drug applications, abbreviated new drug applications, and supplemental new drug applications for TDDS, TMDS, and topical patch products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION: