reports of possible postmarketing adverse events. FDA has determined, under § 314.161, that Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) was withdrawn from sale for reasons of safety or effectiveness.

Braintree discontinued this product containing a total dose of 10 milligrams of bisacodyl from sale after receiving approval from FDA on July 16, 2010, for NDA 21–551/S–013, Halflytely and Bisacodyl Tablets Bowel Prep Kit (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and one bisacodyl delayed release tablet, 5 mg (5-mg bisacodyl)). The data available from a clinical study comparing the 10-mg version of Halflytely and Bisacodyl Tablets Bowel Prep Kit to a 5-mg version of the drug product showed that the Halflytley and Bisacodyl Tablets Bowl Prep Kit (5-mg bisacodyl) has comparable effectiveness to the 10-mg product and has a safety advantage over the 10-mg product because there is less abdominal fullness and cramping in the patients treated with the 5-mg product. Furthermore, the 10-mg product may be associated with ischemic colitis.

FDA has also reviewed the latest approved labeling for the 10-mg product and has determined that it would need to be updated with additional safety information if Braintree were to reintroduce the 10-mg product to the market. FDA has determined that additional clinical studies of safety and efficacy would be necessary before Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) could be considered for reintroduction to the market. Accordingly, the Agency will remove Halflytely and Bisacodyl Tablets Bowel Prep Kit (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 mg) from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20853 Filed 8–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0068; formerly Docket No. 2007D–0290]

Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells; Withdrawal of Draft Guidance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

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

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.

[FR Doc. 2011–20862 Filed 8–16–11; 8:45 am]

BILLING CODE 4160–01–P

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.

FOR FURTHER INFORMATION CONTACT: Terrance Ocheltree, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, rm. 1609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1988.

SUPPLEMENTARY INFORMATION: