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 FDA has determined, under § 314.161, that Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) was withdrawn from sale for reasons of safety or effectiveness.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Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells; Withdrawal of Draft Guidance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:

I. Background

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 TDDS, 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. In the **Federal Register** of August 3, 2010 (75 FR 45640), FDA announced the availability of the draft version of this guidance. The public comment period closed on November 1, 2010. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

Existing TDDS, TMDS, and topical patches contain a larger amount of the drug substance than what is intended to be delivered to the patient. This excess amount of drug substance is needed to facilitate delivery of the intended amount of the drug to the patient and remains as residual drug in the used system. The amount of residual drug substance in TDDS, TMDS, and topical patches has a significant potential to impact the products' quality, efficacy, and safety (including abuse potential). Consequently, it is necessary to ensure that an appropriate scientific approach is used to design and develop these products. The approach should ensure that the amount of residual drug substance is minimized consistent with the current state of technology.

Currently marketed TDDS, TMDS, and topical patches may retain 10 to 95 percent of the initial total amount of drug as the residual drug after the intended use period. This raises a potential safety issue not only to the patient, but also to others, including family members, caregivers, children, and pets. For example, adverse events due to a patient's failure to remove TDDS at the end of the intended use period have been reported and are generally related to an increased or prolonged pharmacological effect of the drug. Also, some children have died from inadvertent exposure to discarded TDDS. Reported adverse events resulting from various quality problems pertaining to TDDS have lead to product recalls, withdrawals, and public health advisories.

To reduce some of these risks, the Agency recommends that a robust design and development approach be considered when developing and manufacturing TDDS, TMDS, and topical patches. One example of such an approach is quality by design, as described in the International Conference on Harmonization guidance for industry entitled ''Q8(R2) Pharmaceutical Development.'' The Agency also recommends that sufficient scientific justification to support the amount of residual drug in TDDS, TMDS, or topical patches be included in an application. The justification should include an evaluation of the safety risks involved with the formulation and system design, as well as support the amount of drug load in the TDDS, TMDS, or topical patch based on the proposed quality target product profile and formulation studies. Most important, the justification for applications of products with known safety issues—such as those with fentanyl-containing liquid reservoir systems—should demonstrate that the safety risk factors have been adequately mitigated.

In all cases, the level of information in the justification should be sufficient to demonstrate product and process understanding and ensure that a scientific, risk-based approach has been taken to minimize the amount of residual drug in a system after use to the lowest possible level. It is expected that the amount of residual drug in a newly developed system (including new generic drug products) will not exceed that of similar FDA-approved products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on residual drug in transdermal and related drug delivery systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Information in an application on the product and process development and justification for the final formulation and system design is approved under OMB control numbers 0910–0001 and 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20852 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–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reorganized the Center for Drug Evaluation and Research (CDER) by establishing four new Divisions under the Office of Generic Drugs. This reorganization includes the organization and their substructure components as listed in this document. This document is announcing the availability of the Staff Manual Guide that explains the details of this reorganization.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 1919 Rockville Pike, Rm. 324, Rockville, MD 20852, 301–796–4422.

SUPPLEMENTARY INFORMATION:

I. Summary

The Statement of Organization, Functions, and Delegations of Authority