An estimated total of 450 new patients (150 patients with HACO MRSA infection and 300 patients without HACO MRSA infection) will be contacted for the MRSA interview annually. This estimate is based on the numbers of MRSA cases reported by the EIP sites annually (*http://www.cdc.gov/abcs/reports-findings/survreports/mrsa08.html*) who are 18 years of age or older, had onset of the MRSA infection in the community or within 3 days of hospital admission, and history of hospitalization in the prior 3 months. There are no costs to respondents other than their time. The total response burden for the study is estimated as follows:

The OMB-approved ABCs MRSA form (#0920–0802) will be used to identify patients to be contacted for a telephone interview. These 450 patients will be screened for eligibility and those considered to be eligible will complete the telephone interview. We anticipate that 350 of the 450 patients screened will complete the telephone interview across all 7 EIP sites per year. We anticipate the screening questions to take about 5 minutes and the telephone interview 20 minutes per respondent.

TABLE—ESTIMATED BURDEN

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
Hospital Patients	Screening Form	450	1	5/60	38
	Telephone interview	350	1	20/60	117
Total					155

Dated: August 10, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–20919 Filed 8–16–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0507]

Determination That Halflytely and Bisacodyl Tablets Bowel Prep Kit (Containing Two Bisacodyl Delayed Release Tablets, 5 Milligrams) Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Halflytely and Bisacodyl Tablets Bowel Prep Kit (polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 milligrams (mg) (10-mg bisacodyl)) was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for bowel prep kits containing PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 mg.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

On September 23, 2010, FDA received a citizen petition (Docket No. FDA–2010–P–0507), submitted under § 10.30 (21 CFR 10.30), from Perrigo Company (Perrigo). The petition requests that the Agency determine whether 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) (Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl)), manufactured by Braintree Laboratories, Inc. (Braintree), was withdrawn from sale for reasons of safety or effectiveness.

Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) (NDA 21–551) was approved on September 24, 2007. Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) was indicated for the cleansing of the colon as preparation for colonoscopy in adults. Braintree informed FDA that it ceased to manufacture and market Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl) as of July 17, 2010. The drug product was then moved to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records concerning the withdrawal of Halflytely and Bisacodyl Tablets Bowel Prep Kit (10-mg bisacodyl). FDA has also independently evaluated relevant literature, data from clinical trials, and

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: