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

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per respondent (in hours)</th>
<th>Total burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Patients</td>
<td>Screening Form</td>
<td>450</td>
<td>1</td>
<td>5/60</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>Telephone interview</td>
<td>350</td>
<td>1</td>
<td>20/60</td>
<td>117</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>155</td>
</tr>
</tbody>
</table>

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Halflytely and Bisacodyl Tablets Bowel Prep Kit (Containing Two Bisacodyl Delayed Release Tablets, 5 Milligrams) Was Withdrawn From Sale for Reasons of Safety or Effectiveness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


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 Halflytely and Bisacodyl Tablets Bowel 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]