Safe or Effectiveness and Other Drug Products Were Not (Dicyclomine Hydrochloride) Syrup DETERMINATION THAT BENTYL [Docket No. FDA–2016–N–2062]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Determination That BENTYL (Dicyclomine Hydrochloride) Syrup and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FDA is requesting approval from the Office of Management and Budget to gather information from Alumni Commissioner’s Fellowship Program (CFP) Fellows. The information from Alumni CFP Fellows will allow FDA’s Office of the Commissioner (OC) to easily and efficiently elicit and review program feedback. The online survey will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner’s Fellow. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of surveys being misrouted within the Agency mail system. The information gathered by the survey will be used to gain insights into, and to document, impacts that the CFP has had and is having on former CFP fellows and contributions and impacts that the former fellows are making in their current work. The surveys include questions to assess the following measures: Post-fellowship employment (e.g., employment type); number of awards; number of contributions while a CFP fellow (e.g., number of publications, guidance authored or co-authored); and contributions in their field (e.g., list of publications).

In the Federal Register of February 24, 2016 (81 FR 9202), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fellowship Program Survey .....................................</td>
<td>35</td>
<td>1</td>
<td>35</td>
<td>0.50 (30 minutes) .....</td>
<td>17.5</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating maintenance costs associated with this collection of information.
21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in this document are no longer being marketed.

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug name</th>
<th>Active ingredient(s)</th>
<th>Strength(s)</th>
<th>Dosage form/ route</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 007961</td>
<td>BENTYL</td>
<td>Hydrochloride</td>
<td>10 milligrams (mg)/5 milliliters (mL).</td>
<td>Syrup; Oral</td>
<td>Aptalis Pharma US, Inc.</td>
</tr>
<tr>
<td>NDA 011721</td>
<td>NEPTAZANE</td>
<td>Methazolamide</td>
<td>25 mg; 50 mg ........................................</td>
<td>Tablet; Oral</td>
<td>Lederle Laboratories.</td>
</tr>
<tr>
<td>NDA 016418</td>
<td>INDERAL</td>
<td>Propranolol HCl</td>
<td>10 mg; 20 mg; 40 mg; 60 mg ...</td>
<td>Tablet; Oral</td>
<td>Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer Inc.</td>
</tr>
<tr>
<td>NDA 021410</td>
<td>AVANDAMET</td>
<td>Rosiglitazone Maleate</td>
<td>500 mg/Equivalent to (EQ) 2 mg base; 500 mg/4 mg base; 1 g/EQ 2 mg base; 1 g/EQ 4 mg base.</td>
<td>Tablet; Oral</td>
<td>SmithKline Beecham (Cork) Ltd, Ireland.</td>
</tr>
<tr>
<td>NDA 021494</td>
<td>AXID</td>
<td>Nizatidine</td>
<td>15 mg/mL ........................................</td>
<td>Solution; Oral</td>
<td>Braintree Laboratories, Inc.</td>
</tr>
<tr>
<td>NDA 050505</td>
<td>GARAMYCIN</td>
<td>Gentamicin Sulfate</td>
<td>EQ 2 mg base/mL .....................................</td>
<td>Injectable; Intrathecal.</td>
<td>Schering-Plough Corp.</td>
</tr>
<tr>
<td>ANDA 061716</td>
<td>GARAMycin</td>
<td>Gentamicin Sulfate</td>
<td>EQ 1 mg base/mL; EQ 40 mg base/fate.</td>
<td>Injectable; Injection.</td>
<td>Schering-Plough Corp.</td>
</tr>
<tr>
<td>ANDA 061739</td>
<td>GARAMycin</td>
<td>Gentamicin Sulfate</td>
<td>EQ 10 mg base/mL ...................................</td>
<td>Injectable; Injection.</td>
<td>Astellas Pharma US, Inc.</td>
</tr>
<tr>
<td>ANDA 080745</td>
<td>ARISTOCORT</td>
<td>Triamcinolone Acetonide</td>
<td>0.5% ........................................</td>
<td>Ointment; Topical.</td>
<td>Delcor Asset Corp.</td>
</tr>
</tbody>
</table>

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–18707 Filed 8–5–16; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0453]

Deciding When To Submit a 510(k) for a Software Change to an Existing Device; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Deciding When to Submit a 510(k) for a Software Change to an Existing Device.” FDA is issuing this draft guidance document to clarify that when a software change in a legally marketed medical device would require that a manufacturer submit a premarket notification (510(k)) to FDA. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments to http://www.regulations.gov.

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows: