SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in the PRA and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;

(2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) uses the information gathered annually from these data collection efforts to provide Congress with the information mandated in GPRA, provide OMB information required for assessment of performance on GPRA indicators, and support its evaluation activities. Data collected from the 10 grant programs will provide a national description of the research activities of approximately 255 NIDILRR grantees. NIDILRR’s GPRA plan must collect information to meet the following mandates: (a) Implementation of a comprehensive plan that includes goals and objectives; (b) measurement of the program’s progress in meeting its objectives; and (c) submission of an annual report on program performance, including plans for program improvement, as appropriate. The data collection system addresses nearly all of the agency’s GPRA indicators, either directly or by providing information for the agency’s other review processes.

The proposed data collection tools may be found on the ACL website for review at https://www.acl.gov/about-acl/public-input.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:


Mary Lazare,
Principal Deputy Administrator.

[FR Doc. 2020–16583 Filed 7–30–20; 8:45 am]
BILLING CODE 4154–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is developing a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need (the 503B Bulks List). Drug products that outsourcing facilities compound using bulk drug substances on the 503B Bulks List can qualify for certain exemptions from the Federal Food, Drug, and Cosmetic Act (FD&C Act) provided certain conditions are met. This notice identifies four bulk drug substances that FDA has considered and proposes to include on the 503B Bulks List: Diphenylcyclopropenone (DPCP), glycolic acid, squaric acid dibutyl ester (SADBE), and trichloroacetic acid (TCA). This notice also identifies 19 bulk drug substances that FDA has considered and proposes not to include on the list: Diazepam, dobutamine hydrochloride (HCl), dopamine HCl, edetate calcium disodium, folic acid, glycopyrrolate, hydroxyzine HCl, ketorolac tromethamine, labetalol HCl, mannitol, metoclopramide HCl, moxifloxacin HCl, nalbuphine HCl, polidocanol, potassium acetate, proacainamide HCl, sodium nitroprusside, sodium thiosulfate, and verapamil HCl. Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and may be the subject of future notices.

DATES: Submit either electronic or written comments on the notice by September 29, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 29, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 29, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “CONFIDENTIAL INFORMATION.” Any information marked “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

<table>
<thead>
<tr>
<th>Type of Submission</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852</td>
<td>75</td>
<td>1</td>
<td>52</td>
<td>3,900</td>
</tr>
<tr>
<td>For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”</td>
<td>124</td>
<td>1</td>
<td>22</td>
<td>2,728</td>
</tr>
<tr>
<td>For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”</td>
<td>76</td>
<td>1</td>
<td>10</td>
<td>760</td>
</tr>
<tr>
<td>Total</td>
<td>275</td>
<td></td>
<td>7,388</td>
<td></td>
</tr>
</tbody>
</table>

Instructions: All submissions received must include the Docket No. FDA–2018–N–3240 for “List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”


Mary Lazare,
Principal Deputy Administrator.

[FR Doc. 2020–16584 Filed 7–30–20; 8:45 am]
BILLING CODE 4154–01–P