Dated: July 27, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–16583 Filed 7–30–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB #0985–0050]

Agency Information Collection Activities; Proposed Collection; Comment Request; The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) Grantee Annual Performance Reporting (APR) and Final Report Forms

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on the Proposed Extension without Change and solicits comments on the information collection requirements related to the NIDILRR Grantee Annual Performance Reporting (APR) and Final Report Forms.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 29, 2020.

ADDRESSES: Submit electronic comments on the collection of information to: Mary Darnell *Mary.Darnell@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Mary Darnell.

FOR FURTHER INFORMATION CONTACT: Mary Darnell, Administration for Community Living, 202–795–7337.

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) Grantee Annual Performance Reporting (APR) and Final Report Forms collect data from all NIDILRR Grantees via a web-based reporting system and addresses specific HHS regulations that shall be met by applicants and grantees. HHS regulations that apply to NIDILRR Grant programs include Part 75 of the Uniform Administrative Requirements, Cost Principles and Audit requirements for HHS Awards. Specifically, § 75.342 which requires grantees to submit an annual performance report or, for the last year of a project, a final report that evaluates: (a) The grantee's progress in achieving the objectives in its approved application, (b) the effectiveness of the project in meeting the purposes of the program, and (c) the results of research and related activities.

Additionally, GPRA requires all federal agencies to implement performance measurement systems that include: (1) A five-year strategic plan, (2) an annual performance plan, and (3) an annual performance report. Currently, NIDILRR has met these requirements and has established performance indicators to meet the reporting requirements. The NIDILRR APR System currently includes reporting forms for all 10 of NIDILRR's grant programs.

Reporting forms for all 10 programs are web-based. Data collected through these forms (a) Facilitate program planning and management; (b) respond to ACL/HHS Grants Policy Administration Manual (GPAM) requirements and (c) respond to the reporting requirements of the Government Performance and Results Act (GPRA) of 1993.

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:

	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Grantees	75	1	52	3.900
Continuations of Major Programs	124	1	22	2,728
Other Continuations	76	1	10	760
Total	275	.....	.....	7,388

Dated: July 27, 2020.

Mary Lazare,

Principal Deputy Administrator.

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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, procainamide 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 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:

- *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.
- 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.''

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.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—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 ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For