Attachment B: Federal Register Notice

suppliers likely to enter this market in the near future. As there is no generic version of Transderm Scop on the market today, it is likely that the price for scopolamine transdermal patches would significantly decrease with the onset of generic competition. Without a remedy, the proposed acquisition would eliminate the price reductions that would likely have accompanied Mylan's independent entry into this market.

II. Entry

Entry into each of these generic pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating current or future competition between Mylan and Perrigo in these seven concentrated markets. In each of these markets, Mylan and Perrigo are two of a limited number of current or likely future suppliers in the United States. Market participants characterize each of the markets as a current or likely future commodity market, in which the number of generic suppliers has a direct impact on pricing. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Mylan and Perrigo currently compete likely would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic drugs.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, Mylan is required to divest to Alvogen its rights to the seven relevant products. Alvogen is an international pharmaceutical company, with commercial operations in thirty-four countries. Its business focuses on developing, manufacturing, and distributing generic, branded, and OTC pharmaceutical products. Mylan must accomplish the divestitures to Alvogen and relinquish its rights to these products no later than thirty days after the proposed acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and to divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee if Mylan fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan must provide transitional services to Alvogen to assist it in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable Mylan employees. Mylan must also provide Alvogen with a supply of the divested products while Mylan transfers manufacturing technology to Alvogen or its designated manufacturer. The goal of the transitional services is to ensure that Alvogen will be able to operate independent of Mylan in the manufacture and sale of the divested products. Nothing in the Consent Agreement, however, precludes Alvogen from sourcing active pharmaceutical ingredients or other divestiture product inputs from Mylan on a negotiated basis.

As Alvogen was unable to perform due diligence on the Perrigo products at issue, Mylan divested its own on-market, generic acyclovir ointment product rather than Perrigo's product in development. Because the competition that is preserved by the proposed Consent Agreement will only occur when the Perrigo product is launched, the proposed Order permits Mylan to retain the right to sell acyclovir ointment through a license from Alvogen until thirty days after Mylan receives approval for the Perrigo ANDA, but for no longer than three years. This provision is designed to permit Mylan to remain an active market participant pending the approval of Perrigo's acyclovir ointment ANDA but also ensures Mylan's continued incentive to develop and launch the Perrigo product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–28522 Filed 11–9–15; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–0943; Docket No. CDC–2015–0098]

Proposed Data Collections Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Study of Long-Term Care Providers. The purpose is to collect data for the residential care community and adult day services center components for the 2016 wave of the National Study of Long-Term Care Providers.

DATES: Written comments must be received on or before January 11, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0098 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Residential Care Community and Adult Day Service Center Components of the National Study of Long-Term Care Providers (OMB Control No. 0920–0943 Exp. Date: 07/31/2015)—Reinstatement with change—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, "shall collect statistics on health resources . . . [and] utilization of health care, including extended care facilities, and other institutions."

NCHS seeks approval to collect data for the residential care community (RCC) and adult day services center (ADSC) survey components of the 3rd wave of the National Study of Long-Term Care Providers (NSLTCP). A two year clearance is requested.

As background here are some details on the complete study design. The NSLTCP, a voluntary survey, is designed to (1) broaden NCHS' ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers and service users (*i.e.*, Centers for Medicare and Medicaid Services (CMS) data on nursing homes and residents, home health agencies and patients, and hospices and patients); (3) update data more frequently on LTC providers and service users for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC sectors and timely monitoring of supply and use of these sectors over time.

Data will be collected from two types of LTC providers in the 50 states and the District of Columbia: 11,690 RCCs and 5,440 ADSCs in each wave. Data were collected in 2012 and 2014. The data to be collected beginning in 2016 include the basic characteristics, services, staffing, and practices of RCCs and ADSCs, and aggregate-level distributions of the demographics, selected health conditions and health care utilization, physical functioning, and cognitive functioning of RCC residents and ADSC participants.

Expected users of data from this collection effort include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and Quality; associations, such as LeadingAge (formerly the American Association of Homes and Services for the Aging), National Center for Assisted Living, American Seniors Housing Association, Assisted Living Federation of America, and National Adult Day Services Association; universities; foundations; and other private sector organizations such as the Alzheimer's Association and the AARP Public Policy Institute.

Expected burden from data collection is 30 minutes per respondent. We estimate that 5% of RCC and ADSC directors will be called for an additional 5 minutes of data retrieval when there are errors or omissions in their returned questionnaires. Two year clearance is requested to cover the collection of data. The burden for the collection is shown in Table 1 below. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
RCC Director/Designated Staff	RCC Questionnaire	5,846	1	30/60	2,923

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
ADSC Director/Designated Staff	ADSC Questionnaire	2,720	1	30/60	1,360
RCC and ADSC Directors/Designated Staff.	Data Retrieval	429	1	5/60	36
Total					4,319

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–28475 Filed 11–9–15; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16CO; Docket No. CDC–2015–0099]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment for Developing a Self-Management Tool for Individuals with Systemic Lupus Erythematosus (SLE), to assess the value of a tool aimed to enhance the ability of persons with SLE to effectively manage their condition.

DATES: Written comments must be received on or before January 11, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0099 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Developing a Self-Management Tool for Individuals with Systemic Lupus Erythematosus (SLE)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body leading to widespread inflammation and tissue damage. SLE has a variety of clinical manifestations and can affect joints, skin, the brain, lungs, kidneys, and blood vessels. Effective SLE management depends not only upon clinical interventions, but also on self-management—those things done on a day-to-day basis to manage SLE. SLE self-management requires gaining essential knowledge, skills, and confidence to manage the condition.

CDC previously launched a two-year project called "*Filling a Gap: Creating*