

**Attachment D: Federal Register Notice**

products are used to treat actinic keratosis (“AK”), which is a precancerous lesion that can result from years of repeated sun exposure. Three branded topical 5FUs are currently on the market, including Valeant’s Efudex and Dermik’s Carac. There are also two generic versions of Efudex, as well as an “authorized” generic, also sold by Valeant. The price of the generic drugs in this market determines the pricing of branded Carac. Post-acquisition, Valeant’s market share in the topical 5FU market would be over 50 per cent. Other treatments for AKs are not viable substitutes for topical 5FUs because they are more costly, less efficacious or impracticable.

**III. Entry**

Entry into the manufacture and sale of both BenzaClin and topical 5FU products is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration approval for the manufacture and sale of topical pharmaceuticals takes over two years due to substantial regulatory, technological and intellectual property barriers. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a new entrant would likely be insufficient to justify the time and investment necessary to enter.

**IV. Effects of the Acquisition**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of both BenzaClin and topical 5FU products by eliminating actual, direct and substantial competition between Valeant and Sanofi in those markets. With respect to the BenzaClin market, the transaction would combine BenzaClin and its only generic equivalent, eliminating BenzaClin’s closest competitor and creating a monopoly. The impact of eliminating the competition between BenzaClin and its only currently-marketed generic equivalent, is highly likely to result in consumers paying higher prices.

In the topical 5FU market, the transaction would give Valeant control over three linked treatments for AK—Dermik’s branded Carac and Valeant’s branded and AG Efudex products. The combination of these products at Valeant would eliminate head to head competition between Carac and the Efudex AG and is thus likely to result in higher prices for topical 5FUs.

**V. The Consent Agreement**

The proposed Consent Agreement effectively remedies the acquisition’s anticompetitive effects in the relevant markets by requiring Valeant to (1) divest its ANDA for generic BenzaClin to Mylan, and (2) supply an authorized generic of Efudex, pursuant to a license to Mylan. If approved, Mylan will acquire all rights and assets currently held by Valeant, including any existing inventory. The assets to be transferred include all manufacturing and research and development rights in the divested products.

Mylan is a particularly well-suited acquirer of generic BenzaClin because it has been manufacturing and marketing the product, pursuant to an agreement with Valeant, since it was introduced in August 2009. Mylan is the second-largest generic pharmaceutical manufacturer in the United States, and is well-positioned to replicate the competition that would be lost with the proposed Valeant/Dermik acquisition. Headquartered in Pittsburgh, Pennsylvania, Mylan employs more than 18,000 employees and generated approximately \$5.45 billion in revenue in 2010. Mylan sells approximately 270 products and has a manufacturing facility where BenzaClin is manufactured. It is in the process of upgrading that facility to handle compounds such as 5FU.

Mylan expects to begin manufacturing generic Efudex at that facility in 2013. Until that time, the proposed Consent Agreement contemplates Mylan’s purchase of topical 5FU from Valeant pursuant to a supply agreement. In order to ensure that there is no supply interruption, the proposed Consent Agreement would require that Valeant build up a two-year inventory and establish its own manufacturing as a back-up supply until Mylan is able to manufacture Efudex commercially. Valeant would also be required to assist Mylan with developing its manufacturing capabilities and securing the necessary FDA approvals. With these provisions, Mylan will be able to compete in the 5FU market immediately following the divestiture and establish independent manufacturing as soon as practicable.

The Commission has appointed Francis J. Civile as the Interim Monitor to oversee the asset transfer and to ensure Valeant’s compliance with the provisions of the proposed Consent Agreement. Mr. Civile has over 27 years of experience in the pharmaceutical industry. He has extensive experience in areas such as pharmaceutical research and development, regulatory approval,

manufacturing and supply, and marketing. Mr. Civile will oversee the transfer of Efudex manufacturing technology to the acquirer and ensure that Valeant is diligent in building up the required inventory of the product and establishing its own back-up supply capabilities. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60-Day 12–12BZ]**

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 639–5960 and send written comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

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; and (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. Written comments should be received within 60 days of this notice.

**Proposed Project**

Residential Care Facility and Adult Day Service Center Components of the National Study of Long-Term Care Providers—NEW—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 facility (RCF) and adult day services center (ADSC)

components of a planned new survey, the National Study of Long-Term Care Providers (NSLTCP). A two year clearance is requested.

As background here are some details on the plans for the whole study, of which this data collection is two components. The entire NSLTCP is being designed to: (1) Broaden NCHS’ ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers (i.e. Centers for Medicare and Medicaid Services (CMS) data on nursing home, home health, and hospice care); (3) update data more frequently on LTC providers for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC provider types and monitor the supply and use of these providers.

The data will be collected in the 50 states and the District of Columbia from two types of LTC facilities: 9,450 RCFs and 4,601 ADSCs. The data to be collected include the basic characteristics, services, staffing, and

practices of RCFs and ADSCs, and aggregate-level distributions of the demographics, physical functioning, and cognitive functioning of RCF and ADSC care recipients.

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.

Expected burden from data collection is 45 minutes per respondent for a total of 5,270 hours. There is no cost to respondents other than their time to participate.

**ESTIMATED ANNUALIZED BURDEN TABLE**

Type of respondent	Form name	Number of respondents	Number of responses	Average burden/ response (in minutes)	Response burden (in hours)
RCF Director .....	RCF Questionnaire .....	4,725	1	45/60	3,544
ADSC Director .....	ADSC Questionnaire .....	2,301	1	45/60	1,726
<b>Total .....</b>					<b>5,270</b>

Dated: December 9, 2011.  
**Daniel Holcomb,**  
*Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30 Day-12-11HU]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written

comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Web-Based HIV Behavioral Survey among Men who have Sex with Men—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

The purpose of the proposed information collection is to monitor behaviors related to Human Immunodeficiency Virus (HIV) infection among men who have sex with men (MSM), one of the groups at highest risk for acquiring HIV infection in the United States. Objectives of the proposed web-based behavioral survey of internet-using MSM are to (a) describe the prevalence of and trends in risk behaviors; (b) describe the prevalence of and trends in HIV testing;

(c) describe the prevalence of and trends in use of HIV prevention services; and (d) identify met and unmet needs for HIV prevention services. This information will be used to monitor progress toward the National HIV/AIDS Strategy objectives, and will be shared with health departments, community based organizations, community planning groups and other stakeholders to improve prevention services.

This project also addresses the goals of CDC’s HIV prevention strategic plan, specifically the goal of strengthening the national capacity to monitor the HIV epidemic to better direct and evaluate prevention efforts.

The Centers for Disease Control and Prevention request approval for data collection for a period of 3 years. Data will be collected through anonymous online surveys completed by MSM in 56 U.S. jurisdictions (all 50 U.S. states, the District of Columbia, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands), with oversampling in 21