

of FDA-imposed New Chemical Entity exclusivity periods, the earliest that any company could file for regulatory approval of a generic iron gluconate product is February 2004. Similar provisions protect iron sucrose, though its exclusivity period expires in November 2003. Entry into the market for the manufacture and sale of NIIRTs is further complicated by a lack of raw material suppliers. Even if a new entrant were to locate a raw material supplier, both iron gluconate and iron sucrose are difficult products that would take more than two years to develop. Wyeth is the best-positioned firm to successfully develop a NIIRT product.

The proposed acquisition is likely to have anticompetitive effects in the market for the manufacture and sale of NIIRTs in the United States because it would eliminate potential competition between Baxter and Wyeth. The proposed acquisition would remove Wyeth as the best-positioned independent entrant into this market and prevent all associated price competition.

The proposed Consent Agreement preserves future competition in the market for the manufacture and sale of NIIRTs by requiring Baxter to terminate its co-marketing agreement with Watson within weeks of the expiration of Ferrlicit®'s New Chemical Entity exclusivity. This termination provides an incentive for Baxter to continue developing and ultimately launch the iron gluconate product that it will acquire from Wyeth.

Pursuant to the terms of the Order, the Commission has appointed William E. Hall as a Monitor Trustee to ensure Baxter's and Wyeth's compliance with all of the requirements of the Order. Mr. Hall has over 30 years of experience in the pharmaceutical industry and is well-respected in the industry. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the Consent Agreement requires Baxter and Wyeth to file reports with the Commission periodically until the divestitures 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 Consent Agreement or to modify its terms in any way.

By direction of the Commission.

C. Landis Plummer,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-03-33]

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 the CDC Reports Clearance Officer on (404) 498-1210.

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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: The Second Injury Control and Risk Survey (ICARIS 2) Phase 2—New—The National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC)—This project will use data from a telephone survey to measure injury-related risk factors and guide injury prevention and control priorities including those identified as priorities in Healthy People 2010 objectives for the nation. Injuries are a major cause of premature death and disability with associated economic costs of over \$150 billion dollars in lifetime costs for persons injured each year. Healthy People 2010 objectives and the recent report from the Institute of Medicine, Reducing the Burden of Injury, call for reducing this toll. In addition to national efforts, NCIPC funds injury control prevention programs at the state and local levels. These programs need data both to establish their prevention

priorities and monitor their performance. The use of outcome data (e.g., fatal injuries) for measuring program effectiveness is problematic because cause-specific events are relatively rare and because data on critical risk factors (e.g., was a helmet worn in a bike crash?; was a smoke detector present at a fatal fire?) are often missing. Because these risk factors are early in the causal chain of injury, they are what injury control programs target to prevent injuries. Accordingly, monitoring the level of injury risk factors in a population can help programs set priorities and evaluate interventions.

The first Injury Control and Risk Factor Survey (ICARIS), conducted in 1994, was a random digit dial telephone survey that collected injury risk factor and demographic data on 5,238 English- and Spanish-speaking adults (greater than or equal to 18 years old) in the United States. Proxy data were collected on 3,541 children <15 years old. More than a dozen peer-reviewed scientific reports have been published from the ICARIS data on subjects including dog bites, bicycle helmet use, residential smoke detector usage and fire escape practices, attitudes toward violence, suicidal ideation and behavior, and compliance with pediatric injury prevention counseling.

ICARIS-2, a national telephone survey about injury, which began in the summer of 2000, has collected data on more than 8,700 of the targeted 10,200 respondents to date. The first phase of the survey was initiated as a means for monitoring the injury risk factor status of the nation at the start of the millennium. The second phase of the survey is needed to expand knowledge in areas investigators could not fully explore, previously. By using data collected in ICARIS as a baseline, data collected in ICARIS-2 Phase-2 will be used along with data currently being collected (ICARIS-2 Phase-1) to measure changes and gauge the impact of injury prevention policies. The ICARIS-2 surveys may also serve as the only readily available source of data to measure several of the Healthy People 2010 injury prevention objectives. In order to more fully monitor injury risk factors and selected year Healthy People 2010 injury objectives, as well as evaluate the effectiveness of injury prevention programs, the second phase (ICARIS-2 Phase-2) of the current national telephone survey on injury risk is being implemented. The only cost to the respondents is the time involved to complete the survey.