reserve their heavy hand for conduct that falls within standards for *per se* illegality clearly enunciated by the Supreme Court. Accordingly, I cannot support the proposed enforcement action made public today.

[FR Doc. 97–3341 Filed 2–10–97; 8:45 am]
BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–28]

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 Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

The following request has been submitted for review since the last publication date on February 4, 1997.

Proposed Project

1. Biomechanical Stress Control in Drywall Installation—New-Drywall installers represented approximately 1.42% of the construction workforce in 1992. Based on analysis of the Supplementary Data System (BLS) of 21 states, the compensable injury/incidence rate (27.5 cases per 100 workers for this group) was nearly three times the injury rate of 9.5 for all other construction occupations combined, in 1987. Data from the 1992 and 1993 Annual Survey of Occupational Injuries and Illnesses (BLS) indicated that there were an estimated 4,680 traumatic injuries among drywall installers involving days away from work in the construction industry in 1992, and 4,122 in 1993. In 1993, bodily reaction and exertion (31.8%), falls (28.6%), and contact with objects (24.6%) were the leading events of injury and illness involving days away from work. As a result, sprains and strains (40.6%) constituted the most frequent nature of injuries and illnesses category in 1994.

To gain an understanding of these injuries, NIOSH has initiated this project to examine different approaches in both field and laboratory settings to identify and control the high-risk activities associated with the traumatic injuries and overexertion hazards of drywall installation work. One of the field study components for this project is to identify high-risk tasks and activities for drywall installers, using a drywall installation survey which was developed at NIOSH. The findings of this survey will provide further understanding and focus laboratory research efforts on the most hazardous tasks/activities of drywall-installation work. Study populations will include drywall installers or construction workers with drywall installation experience. Each questionnaire will take approximately 20 minutes to complete. The total annual burden is 30.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Drywall Installers	120	1	.25

Dated: February 5, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–3332 Filed 2–10–97; 8:45 am]
BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96E–0388]

Determination of Regulatory Review Period for Purposes of Patent Extension; MERREM® I.V.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MERREM® I.V. and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MERREM® I.V. (meropenem). MERREM® I.V. is indicated as single agent therapy for the treatment of the following infections