

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

when caused by susceptible strains of the following designated microorganisms: Intra-abdominal Infections: Complicated appendicitis and peritonitis caused by viridans group streptococci, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Bacteroides fragilis*, *B. thetaiotaomicron*, and *Peptostreptococcus* species. Bacterial Meningitis (pediatric patients  $\geq$  3 months only): Bacterial meningitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* ( $\beta$ -lactamase and non- $\beta$ -lactamase-producing strains), and *Neisseria meningitidis*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MERREM® I.V. (U.S. Patent No. 4,943,569) from Sumitomo Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 4, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MERREM® I.V. represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MERREM® I.V. is 2,608 days. Of this time, 1,640 days occurred during the testing phase of the regulatory review period, while 968 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 3, 1989. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on May 3, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357):* October 28, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for MERREM® I.V. (NDA 50-706) was initially submitted on October 28, 1993.

3. *The date the application was approved:* June 21, 1996. FDA has verified the applicant's claim that NDA 20-506 was approved on June 21, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and

Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,063 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 14, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 11, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 31, 1997.

Stuart L. Nightingale,  
Associate Commissioner for Health Affairs.  
[FR Doc. 97-3313 Filed 2-10-97; 8:45 am]  
BILLING CODE 4160-01-F

#### [Docket No. 96E-0360]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Topical Gel

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Topical Gel 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 DIFFERIN Topical Gel (adapalene). DIFFERIN Topical Gel is indicated for the topical treatment of acne vulgaris. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DIFFERIN Topical Gel (U.S. Patent No. 4,717,720) from Centre International de Recherches Dermatologiques (CIRD), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Topical Gel represented the first permitted commercial marketing or use of the product. Shortly thereafter, the