(HP) objectives for adults (HP 2010: 21–3, 21–4, 21–10), to monitor reported use of a key preventive service for adults (teeth cleaning), and to examine the relationship of oral health indicators to general health status, conditions, and behaviors.

As more state dental programs consider the oral health of adults, states have requested that a bank of additional standardized questions be created to monitor other oral health indicators. CDC/DOH has been reluctant to provide additional technical assistance, without firm data on the reliability and validity of questions. Because all BRFSS questions require self-report by respondents about their own oral health status or behaviors, recall bias and errors in perception exist. To accomplish estimates of response error, answers to existing and proposed BRFSS questions (limit = 10 content questions, plus 7 demographic questions) must be compared to the ''True'' situation of that individual, *i.e.*, that is found in patient charts or other clinical records.

The proposed data collection and analysis will be conducted through the Alliance of Community Health Plans by research foundations affiliated with two dental plans, Kaiser Permanente Northwest, Portland, OR and Health Partners, Minneapolis, MN. The proposed telephone survey, similar to BRFSS, of a convenience sample of 400 dental plan members (200 from each respective HMO) would occur only once. Neither published studies nor informal discussions with dental researchers regarding work in progress uncovered any information that would eliminate the need for this data collection. All work on this project, including linkages between health plan records and responses to the BRFSS questions, will be conducted at the research foundations associated with the respective health plans. CDC will receive only a report on the validity of the questions, and will not have access to the database constructed for the contract.

Study findings will allow CDC to respond to state requests for inclusion of additional standardized questions in an optional oral health module for BRFSS and ensure that any such questions are reliable, valid, and useful for state program planning and evaluation. There is no cost to respondents.

Health plan respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Kaiser Northwest	200	1	15/60	50
Health Partners	200	1	15/60	50
Total				100

Dated: July 28, 2002.

Thomas A. Bartenfeld,

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

[FR Doc. 03–19580 Filed 7–31–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0036]

Determination of Regulatory Review Period for Purposes of Patent Extension; SPECTRACEF

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPECTRACEF 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Director 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 SPECTRACEF (cefditoren pivoxil). SPECTRACEF is indicated for treatment of acute exacerbation of chronic bronchitis, pharyngitis/tonsillitis, and uncomplicated skin and skin structure infections. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SPECTRACEF (U.S. Patent No. 4,839,350) from Meiji Seika Kaisha, 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 February 4, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SPECTRACEF 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 SPECTRACEF is 1,461 days. Of this time, 851 days occurred during the testing phase of the regulatory review period, while 610 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 (the act) (21 U.S.C. 355(i)) became effective*: August 31, 1997. The applicant claims August 30, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 31, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 29, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for SPECTRACEF (NDA 21–222) was initially submitted on December 29, 1999.

3. *The date the application was approved*: August 29, 2001. FDA has verified the applicant's claim that NDA 21–222 was approved on August 29, 2001.

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 1,032 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by January 29, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 29, 2004. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Copies are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 14, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–19621 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Medical Device User Fee Rates for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2004. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorizes FDA to collect user fees for certain medical device applications. The FY 2004 fee rates are provided in this notice. For all applications submitted on or after October 1, 2003, and through September 30, 2004, fees must be paid at the FY 2004 rates at the time that applications are submitted to FDA. It is the date that the application is received by FDA, not the date that the check is received, that governs the fee that must be paid. This notice provides details on how fees for FY 2004 were determined and payment procedures for those submitting medical device applications subject to user fees.

FOR FURTHER INFORMATION CONTACT:

For further information on MDUFMA: Visit the FDA Web site at *http://www.fda.gov/oc/mdufma*.

For questions relating to this notice: Frank Claunts, Office of Management and Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 U.S.C. 379j), establishes fees for different kinds of medical device applications. Fees are assessed on certain types of medical device applications and supplements. When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

For FY 2003 through FY 2007, MDUFMA (Public Law 107–250) establishes revenue amounts for the aggregate of all application fee revenues. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation, workload, and compensation for revenue shortfalls from previous years. Fees for applications are to be established each year by FDA so that revenues will approximate the levels established in the statute, after those amounts have been first adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

This notice establishes fee rates for FY 2004. These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004.

II. Revenue Amount for FY 2004, and Adjustments for Inflation, Workload, and Compensation for Revenue Shortfalls from Previous Fiscal Years

A. Statutory Fee Revenue Amount

MDUFMA specifies that the fee revenue amount for FY 2004 is $27,255,000, before any adjustments are made (21 U.S.C. 379j(b)).

B. Inflation Adjustment to Fee Revenue Amount

MDUFMA provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of: (1) The total percentage change that occurred in the Consumer Price Index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the FY for which fees are being set, or (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area. MDUFMA provides for this annual adjustment to be cumulative and compounded annually after 2003 (see 21 U.S.C. 379j(c)(1)).

The inflation adjustment for FY 2004 is 4.27 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2003—which was 2.11 percent) or the increase in pay for the previous FY (2003) for Federal employees stationed in the Washington, DC metropolitan area (4.27 percent). No compounding is applied to this amount because there was no inflation increase applied in FY 2003.

The inflation-adjusted revenue amount for FY 2004 is the statutory fee