

(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.*

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## 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.gov/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