to implement appropriate administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality of the data and to prevent unauthorized access to the data.

In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the CMS system. For computerized records, safeguards have been established in accordance with HHS standards and National Institute of Standards and Technology guidelines; e.g., security codes will be used, limiting access to authorized personnel. System securities are established in accordance with HHS, Information Resource Management Circular #10, Automated Information Systems Security Program; CMS Information Systems Security, Standards Guidelines Handbook and OMB Circular No. A–130 (revised) Appendix III.

RETENTION AND DISPOSAL:

CMS will retain identifiable WCSAF data for a period of 6 years and 3 months unless the injured individual becomes a Medicare beneficiary prior to that period of time. When either of these criteria is met, the information stored on the injured individual will be deleted from the WCSAF.

SYSTEM MANAGER(S) AND ADDRESS:

CMS, Center for Medicare Management, Benefits Operations Group, Director, Division of Benefit Coordination, S1–05–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), address, date of birth, date of WC injury/incident, diagnosis, effective date and amount of the WC Set-aside Arrangement. (Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

The Electronic Correspondence Referral System (ECRS), Medicare contractors and the Coordination of Benefit Contractor (COBC), Common Working File, CMS Regional Offices (RO), Medicare beneficiaries and non-Medicare beneficiaries that have an approved WC Set-aside Arrangement to cover future medical costs resulting from an injury incurred while employed and the Social Security Administration (SSA).

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–13190 Filed 5–24–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–1086]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ENBREL 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 which claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4565.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product ENBREL (etanercept). ENBREL is indicated for the reduction in signs and symptoms of moderately to severely active rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying antirheumatic drugs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ENBREL (U.S. Patent No. 5,712,155) from Immunex Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 7, 2000, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ENBREL 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 ENBREL is 2,322 days. Of this time, 2,143 days occurred during the testing phase of the regulatory review period, while 179 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*: June 26, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 26, 1992.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: May 8, 1998. The applicant claims March 9, 1998, as the date the product license application (BLA) for ENBREL (BLA 98–0286) was initially submitted. However, FDA records indicate that BLA 98–0286 was submitted on May 8, 1998.

3. *The date the application was approved*: November 2, 1998. FDA has verified the applicant's claim that BLA 98–0286 was approved on November 2, 1998.

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 240 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may, on or before July 29, 2002, submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 25, 2002, 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. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday

Dated: April 17, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–13227 Filed 5–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office, in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled ''Medical Device Workshop.'' This public workshop is intended to provide information about FDA's medical device quality systems regulation (QSR) to regulated industry and, in particular, to small businesses.

Date and Time: The public workshop will be held on July 19, 2002, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Texas A&M University Health Science Center, Baylor College of Dentistry, 3302 Gaston Ave., sixth floor, Dallas, TX 75246. Directions to the facility are available on the Internet at the Texas A&M University Health Science Center, Baylor College of Dentistry at http://www.tambcd.edu/.

Contact: David Arvelo or Sue Thomason, Southwest Regional Office (HFR–SW16), Food and Drug Administration, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247, 214–655–8100, ext. 130 or 128, FAX 214–655–8114, or e-mail: oraswrsbr@ora.fda.gov.

Registration: Preregistration by June 7, 2002, is encouraged. FMDIC has a $150 preregistration fee. To preregister, please complete the form provided in this document and send it along with a check or money order for $150 payable to the FMDIC, c/o FDA/SWR/Small Business Representative, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247. As an alternative, the registration form can also be obtained on the Internet at http://www.geocities.com/Eureka/Suite/3316/. Seats are limited. Please submit registration forms as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive written confirmation. Registration will close once the course is filled. Onsite registration will be done on a space-available basis on the day of the public workshop beginning at 8:30 a.m. The cost of registration at the site is $175, payable to the FMDIC. If you need special accommodations due to a disability, please contact David Arvelo or Sue Thomason at least 7 days in advance.

The following information is requested for registration purposes:

Name: _____

Company: _____

Mailing address: _____

City: _____ State: _____ Zip code: _____

Phone: _____ FAX: _____

E-mail: _____