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: _____

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest that small medical device manufacturers in the Dallas District area have expressed in the topics that will be addressed at the workshop. FMDIC and FDA will present this workshop to help achieve objectives set forth in section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), because it is an outreach activity by a government agency directed at small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the QSR (21 CFR part 820). Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Analysis of FDA 483s, (2) analysis of FDA warning letters, (3) how corrective and preventive actions (CAPA) relates to QSR and the Quality System Inspection Technique, (4) designing and implementing a CAPA system, and (5) the role of complaint files in a CAPA system.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, starting approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: May 22, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13282 Filed 5–22–02; 3:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request; Retrovirus Epidemiology Donor Study (REDS): A Study of Motivations and Deterrents to Blood Donation in the United States

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 29, 2001, pages 29, 152–29, 153 and allowed 60-days for public comment. The Institute mailed a summary of the protocol and copies of the survey instrument in response to a request. Additionally, the Institute received two comments. A professional association applauded the agency's efforts and urged the Institute to consider future population based studies that would account for views of those who never donate blood. The second comment was from an individual representing biomedical services of a national blood banking institution. This individual stressed the need to build upon previous research conducted by this blood banking organization. The Institute responded to both comments via letter. To the first the Institute replied that they were discussing future studies to assess reasons that some people never donate blood. To the second they responded that while it would be beneficial to build upon this previous data, published literature on this blood collection organization's research was not available. No further responses to the Institute were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Retrovirus Epidemiology Donor Study (REDS): A Study of Motivations and Deterrents to Blood Donation in the United States. Type of Information Collection Request: NEW. Need and Use of Information Collection: There are serious blood shortages in the U.S. and the situation is predicted to worsen unless corrective measures are initiated. Through a randomized mail survey of individuals who have donated blood at one of the blood centers participating in the NHLBI Retrovirus Epidemiology Donor Study (REDS), this study will examine the personal, or intrinsic reasons for choosing to donate blood, as well as external influences for choosing to donate blood. Donors will be given the option to respond via a mailed survey or a secured website. Comparisons will be made between lapsed and repeat donors with the premise that repeat donors may have a stronger altruistic impetus for donating than donors who donate less frequently or discontinue donating. Donors will be asked about factors influencing them to donate, the donation experience, and questions addressing accessibility to donate. Additionally, the study will examine possible barriers to donation, such as inconvenience, discomfort, and confidentiality. With the majority of the blood supply coming from committed, repeat donors, information regarding why an individual decides to donate, and more importantly, what motivates them to come back, will provide valuable insight on possible strategies to encourage increased donation frequency among the current blood donor population. Assessment of possible barriers to donation will provide areas for focusing improvement in the blood donation process. Data from this survey will provide a valuable perspective for devising strategies to increase blood donation the U.S., thus helping insure that there is an adequate supply to meet the needs of the American public. Frequency of Response: Once. Affected Public: Individuals. Type of Respondents: Adult Blood Donors. The annual reporting burden is as follows: Estimated Number of Respondents: 40, 000; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: 0.25; and Estimated Total Annual Burden Hours Requested: 10,000. The annualized cost to respondents is estimated at: $157,000. There are no Capital Costs, Operating Cost, and/or Maintenance Costs to report.