(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

4. Objectives (10 percent). The extent to which the applicant describes long and short term objectives that are specific, measurable, attainable, and realistic. The extent to which objectives are time-framed process and outcome objectives designed to accomplish all activities of the program.

5. Evaluation (10 percent). The extent to which the proposed evaluation plan is detailed and capable of documenting program process and outcome measures. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

6. Performance Goals (10 percent). The extent to which the applicant provides measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome.

7. Budget and Justification (Not Scored). The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

8. Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, by April 15th. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC Web site.

AR–7—Executive Order 12372 Review
AR–8—Public Health System Reporting Requirements
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions
AR–13—Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR–14—Accounting System Requirements
AR–15—Proof of Non-Profit Status

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Nancy Pillar, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2721, E-mail address: *nfp6@cdc.gov*.

For program technical assistance, contact: Stacy L. Harper, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway NE., Mailstop F41, Atlanta, GA 30341–3724, Telephone: 770–488–4031, E-mail address: *SLHarper@cdc.gov*.

Dated: May 1, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–11262 Filed 5–6–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0064]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRACLEER 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 Dockets Management Branch (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 V. 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 TRACLEER (bosentan). TRACLEER is indicated for the treatment of pulmonary arterial hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TRACLEER (U.S. Patent No. 5,292,740) from Hoffman-La Roche, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TRACLEER 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 TRACLEER is 2,176 days. Of this time, 1,807 days occurred during the testing phase of the regulatory review period, while 369 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: December 8, 1995. The applicant claims December 9, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 8, 1995, 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 of the act*: November 17, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for TRACLEER (NDA 21–290) was initially submitted on November 17, 2000.

3. *The date the application was approved*: November 20, 2001. FDA has verified the applicant's claim that NDA 21–290 was approved on November 20, 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 1,259 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by July 9, 2003. 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 November 3, 2003. 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 mailed 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: March 31, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–11215 Filed 5–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0112]

Draft ''Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols'' dated May 2003. This draft guidance document is intended to explain when and how sponsors of clinical trials for certain products can request that FDA engage an independent consultant to participate in the review of protocols for clinical studies intended to serve as the primary basis of claims of efficacy.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by August 5, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; or the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (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: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or John Jenkins, Center for Drug Evaluation and Research (HFD–020), 1451 Rockville Pike, Rockville, MD 20852–1448, 301–594–5421.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols''