procurement to Mathematics Policy Research, Inc. (MPR) with a subcontract to Columbia University's Center for Young Children and Families. The evaluation will be carried out from October 1, 1995 through March 30, 2002. Data collection activities that are the subject of this **Federal Register** notice are intended for the fourth phase of the EHS evaluation. The sample for the assessments will be approximately 1,144 fathers from the 3,000 EHS sample families, whose mothers and infants/toddlers are participating in the study (see OMB #0970–0143) in 13 of the EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The 36-month father assessments will be conducted through personal interviewing, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to better understand the roles of fathers and father-figures with their children and in the EHS program.

Respondents: Fathers or father-figures of children whose families are in the EHS national evaluation sample (both program and control group families).

ANNUAL BURDEN ESTIMATES

Instrument	Estimated number of respondents	Number of responses per respondent	Average burden hours per respondent	Total burden hours
36-month father interview	89	1	1.0	89
36-month interview and videotaping protocol	74	1	1.3	96
36-month abbreviated interview and videotaping protocol	30	1	1.05	32
Estimated Total Annual Burden: 217.				

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: November 20, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–31566 Filed 11–25–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0480]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 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 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 Tasmar® (tolcapone). Tasmar® is indicated for use as an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Tasmar® (U.S. Patent No. 5,236,952) 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 September 15, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Tasmar® 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 Tasmar® is 2,618 days. Of this time, 2,014 days occurred during the testing phase of the regulatory review period, while 604 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 1, 1990. The applicant claims November 28, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 1, 1990, 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*: June 5, 1996. The applicant claims June 3, 1996, as the date the new drug application (NDA) for Tasmar® (NDA 20–697) was initially submitted. However, FDA records indicate that NDA 20–697 was submitted on June 5, 1996.

3. *The date the application was approved*: January 29, 1998. FDA has verified the applicant's claim that NDA 20–697 was approved on January 29, 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 530 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 26, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 26, 1999, 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 (address above) in three copies (except that individuals may submit single copies) and 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: November 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–31576 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0965]

United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128; 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 ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*,'' December 1997. The International Council for Commonality in Blood Banking Automation (ICCBBA) has submitted the draft document to FDA with a recommendation that it serve as the basis for current FDA guidance on the labeling of blood and blood components. The ICCBBA recommends that the bar coding system described in the draft document, ''ISBT 128,'' replace the coding system ''ABC Codabar'' currently in use for blood and blood components. FDA is considering updating its guidance on blood labeling and is issuing this notice to invite public comment on the ICCBBA's draft document and the ''ISBT 128'' coding system, as well as issues related to the possible transition from the labeling of blood and blood components using the ''ABC Codabar'' to a new coding system.

DATES: Written comments may be submitted at any time, however, to ensure comments are adequately considered in the preparation of guidance, comments should be submitted by February 25, 1999.

ADDRESSES: Submit written requests for single copies of the draft document ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*'' 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. Send one self-addressed adhesive label to assist that 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 fax 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 document.

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

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published in the **Federal Register** of August 30, 1985 (50 FR 35472), a notice of availability of a document entitled ''Guideline for the Uniform Labeling of Blood and Blood Components,'' which described the uniform container label for blood and blood components. The standard labels recommended in the guideline for blood and blood components incorporated bar code symbology known as ABC Codabar.

The International Society for Blood Transfusion (ISBT) was organized to bring together professionals involved in blood transfusion medicine. One of the Society's goals is to promote and to maintain a high level of ethical, medical, and scientific standards in blood transfusion medicine and science throughout the world. In August 1989, an ISBT Working Party on Blood Banking Automation recognized that Codabar was becoming outdated and initiated the design of a totally new system named ISBT 128 using the bar code symbology known as Code 128. The *ISBT 128 Technical Specification* document was accepted by the ISBT Council in July 1994.

In November 1994, the ISBT turned over to the ICCBBA the responsibility for worldwide management and distribution of the *ISBT 128 Technical Specification* and associated databases. ICCBBA is a nonprofit group organized to oversee, maintain, and distribute the ISBT 128 system. ICCBBA submitted a draft document to FDA that proposes that ISBT 128 replace the current ABC Codabar system used on blood and blood component labels in the United States. On March 23, 1995, FDA asked the Blood Products Advisory Committee