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

(BPAC) whether FDA should support conversion from the ABC Codabar system to the ISBT 128 system. BPAC voted in favor of FDA supporting the transition to the new coding system. The change to ISBT 128 is also supported by the American Association of Blood Banks (AABB), American Red Cross (ARC), America's Blood Centers (ABC), and the Department of Defense (DoD).

In December 1996, ICCBBA held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although consensus was obtained for use of ISBT 128 as proposed in the draft document, concerns were expressed regarding implementation timeframes and costs of implementation to hospital transfusion services. The ICCBBA submitted a draft of the industry consensus document to FDA with the recommendation that it serve as the basis for current FDA guidance on blood and blood component labeling. The agency is making this draft document describing the use of ISBT 128 in the labeling of blood and blood components available for public comment to assist the agency in determining whether to update its guidance on blood labeling.

Under FDA's ''Good Guidance Practices'' (GGP's), published in the **Federal Register** on February 27, 1997 (62 FR 8961), this draft document is being made available for public comment. The GGP's provide that members of the public may comment on and suggest areas for guidance development or revision and submit draft guidance for possible adoption by the agency. In its discretion, FDA may choose to publish for comment such a draft document as the agency considers whether or not to develop or revise guidance. In this instance, FDA believes it would be helpful to obtain public comment on the ISBT 128 coding system as the agency considers updating its guidance on blood labeling.

II. Request for Comments

FDA is making available for comment this draft document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*.'' In addition to comments about the adoption of ISBT 128 as a blood coding system and the proposed label format, FDA specifically requests comments on the following: (1) The proposed ''rule-based'' system for naming blood components since adoption of ISBT 128 would entail changing some of the currently accepted names of blood components, e.g., Platelets, Pheresis would become Apheresis Platelets; and (2) timeframes and procedures for the transition and full implementation of ISBT 128. FDA notes that its intent would be to initiate changes to language in order to permit the use of the new system if FDA determines the ISBT 128 is an acceptable coding system. Thus, in a future document FDA may consider changes to accommodate the new system of blood component bar coding, identification, and naming.

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft document. Written comments may be submitted at any time, however, comments should be submitted by February 25, 1999, to ensure adequate consideration in the preparation of guidance. Received comments will be considered in determining whether to issue guidance. Two copies of any comments 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. A copy of the draft document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: November 18, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31571 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–50 and HCFA–1515/1572]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medical Records Review Under PPS and Supporting Regulations in 42 CFR 412.40–412.52; Form No.: HCFA-R–0050 (OMB# 0938–0359); Use: Peer Review Organizations (PRO) are authorized to conduct medical review activities under the Prospective Payment System (PPS). In order to conduct the medical review activities we depend upon hospitals to make available medical records. PROs ensure that admissions are medically necessary, provided in the appropriate setting, and that they meet acceptable standards of quality.; Frequency: When records are reviewed; Affected Public: Business or other for profit; Number of Respondents: 7,053; Total Annual Responses: 895,419; Total Annual Hours: 26,865.

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Home Health Agency Survey and Deficiencies Report, Home Health Functional Assessment Instrument and Supporting Regulations in 42 CFR 484.10—484.52; Form No.: HCFA–1515/1572 (OMB# 0938–0355); Use: In order to participate in the Medicare program as a Home Health Agency (HHA) provider, the HHA must meet Federal Standards. These forms are used to record information about patients' health and provider compliance with requirements.; Frequency: Annually; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 9,942; Total Annual Responses: 19,884; Total Annual Hours: 19,884.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your