www.fda.gov/cder/calendar/meeting/rx2000. A transcript and summary of the meeting may be seen at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Marcia L. Trenter, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301–827–1674, or e-mail: trenterm@cder.fda.gov).

SUPPLEMENTARY INFORMATION: Inadequate access to useful patient information is a major cause of inappropriate use of prescription medicines, leading to serious personal injury and costs to the health care system. While the rate of distribution of written prescription drug information materials has increased somewhat over the past 15 years, the quality of such material has been quite variable.

In the **Federal Register** of August 24, 1995 (60 FR 44182), FDA published a proposed rule that aimed to increase the quality and quantity of written information about prescription medicines given to patients. In the proposed rule, entitled ''Prescription Drug Product Labeling; Medication Guide Requirements,'' FDA encouraged the private sector to develop and distribute patient-oriented written information leaflets for all prescription drugs, and set targets for the distribution of these leaflets. In addition to setting target distribution goals by specific dates, the proposed rule set criteria by which written information would be judged to determine whether it was ''useful'' and should therefore count toward accomplishment of the target goals.

In August 1996, the U.S. Congress passed Public Law 104–180 mandating that the private sector be given the opportunity to meet distribution and quality goals for written patient prescription medicine information. It also directed that the Secretary of Health and Human Services (the Secretary) facilitate the development of a long-range comprehensive action plan to meet these goals through private-sector efforts.

The Secretary asked the Keystone Center to convene a Steering Committee to collaboratively develop this action plan. The Action Plan accepted by the Secretary in January 1997 reiterated the target goals specified in the Federal legislation. These goals were that by the year 2000 useful written information would be distributed to 75 percent of individuals receiving new prescriptions for medicines, and by the year 2006 to 95 percent of such individuals. The Action Plan generally endorsed the conceptual criteria specified in Public Law 104–180 for defining the usefulness of medication information. Specifically, it stated that such materials should be: (1) Scientifically accurate; (2) unbiased in content and tone; (3) sufficiently specific and comprehensive; (3) presented in an understandable and legible format that is readily comprehensible to consumers; (4) timely and up to date; and (5) useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. The Action Plan, including descriptions of the criteria, is available on the Internet at http://www.nyam.org/library/keystone.

Consistent with Public Law 104–180, the Action Plan called for the development of a mechanism to periodically assess the quality of written prescription information for patients. To test a methodology for collecting patient information materials and assessing their usefulness, FDA developed a contract with the National Association of Boards of Pharmacy. The contract called for the selection of several State Boards of Pharmacy who would arrange for collecting, from a sample of State pharmacies, medication information materials given with new prescriptions for three commonly prescribed prescription drugs. The contract also called for the development of evaluation materials to assess the usefulness of the information through application of the Action Plan criteria. The medication information materials were collected in 1999, and the final report from the evaluation was completed in December 1999. The report is available on the Internet at http://www.fda.gov/cder/calendar/meeting/rx2000.

FDA is seeking comments on several issues:

- What should be the minimum standard or threshold that must be met for written information to be considered useful?
- Should certain criteria derived from the Action Plan recommendations be given more weight than others? If so, which criteria should be weighted more strongly, and why?
- Are the evaluation forms an accurate translation of the Action Plan's criteria?
- Should the assessment include additional criteria or types of information, and, if so, what?
- Should there be a more detailed assessment of factors affecting readability and legibility for consumers (e.g., type size, style, spacing, contrast)?
- Should the evaluation panel include consumers with varying educational backgrounds? If so, how should they be involved in the evaluation process?
- This report collected patient information from U.S. retail pharmacies. Are there ways to expand sampling to include mail-order or other nonretail pharmacies?

A transcript and summary of the meeting may be seen at the Dockets Management Branch (address above) and they will be available approximately 10 working days after the meeting at a cost of 10 cents per page. Also, received comments may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–3171 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–0241]

Determination of Regulatory Review Period for Purposes of Patent Extension; Wallstent Coronary Endoprosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Wallstent Coronary Endoprosthesis 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 medical device.

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 V. Grillo, Regulatory Policy Staff (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Wallstent Coronary Endoprosthesis. Wallstent Coronary Endoprosthesis is indicated for use following suboptimal percutaneous transluminal angioplasty of common and/or external iliac artery stenotic lesions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Wallstent Coronary Endoprosthesis (U.S. Patent No. 4,954,126) from Boston Scientific 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 March 9, 1999, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Wallstent Coronary Endoprosthesis 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 Wallstent Coronary Endoprosthesis is 1,533 days. Of this time, 1,351 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: July 21, 1994. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective July 21, 1994.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): April 1, 1998. The applicant claims March 31, 1998, as the date the premarket approval application (PMA) for Wallstent Coronary Endoprosthesis (PMA P980009) was initially submitted. However, FDA records indicate that PMA P980009 was submitted on April 1, 1998.

3. The date the application was approved: September 29, 1998. FDA has verified the applicant's claim that PMA P980009 was approved on September 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 857 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 11, 2000, 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 August 9, 2000, 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: December 23, 1999.

Jane A. Axelrad,

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

[FR Doc. 00–3172 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0186]

International Conference on Harmonisation; M4 Common Technical Document; Request for Comments on Initial Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of initial components of a draft guidance [1] entitled ''M4 Common Technical Document,'' which is being developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Because of the large size of the draft guidance, FDA is making some components of the draft guidance available to the public at this time to help explain the overall scheme of the draft guidance and to request comments. When completed, the guidance entitled ''M4 Common Technical Document'' will describe a harmonized format and content for designated new product applications for submission to the regulatory authorities in the three ICH regions. The agency intends to make the entire draft guidance available to the public for comment once all the components have been drafted.

DATES: Submit written comments on the initial components of the draft guidance by March 13, 2000.

ADDRESSES: Submit written comments on these components of the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. An electronic version of the components is available on the Internet at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/publications.htm.

[1] In accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997), ICH guidance documents are now being called guidances, rather than guidelines.