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.

FOR FURTHER INFORMATION CONTACT: For the safety components: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

For the quality components: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2570, and Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

For the efficacy sections: Robert J. DeLap, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2250.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies.

ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Therapeutics Products Programme, and the European Free Trade Area.

The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. However, until recently, the application documents in the three ICH regions had not been examined, and there are significantly different requirements in each region for the composition and organization of product applications. As a result, three Expert Working Groups for Quality, Safety, and Efficacy have been developing harmonized guidance for the content and format of common sections of an application, called the ''common technical document.'' Once finalized, the guidance entitled ''M4 Common Technical Document'' will describe an acceptable format and content for applications for human pharmaceuticals that, once supplemented with regional particulars, can be used with designated new products for submission to the regulatory authorities in the three ICH regions.

The ICH Steering Committee is overseeing the work on the common technical document through the use of milestones that reflect the stages of completion as work proceeds. A key goal is to ensure that the process for developing the common technical document is transparent. As part of this transparency, the ICH Steering Committee agreed, in October 1999, that the components of the draft guidance entitled ''M4 Common Technical Document'' be made available for public comment as they evolve. The components being made available by this notice are the product of the Quality, Safety, and Efficacy Expert Working Groups of the ICH. Received comments on these components will be considered by FDA and the appropriate expert working group as the draft guidance ''M4 Common Technical Document'' is finished. Once it is finalized, the guidance entitled ''M4 Common Technical Document'' will describe the format and content for a common technical document that, when supplemented by regional information, is suitable for submission to the regulatory authorities in the three ICH regions.

II. Organization of the Common Technical Document

The common technical document should be viewed as the common part of a submission for designated new products, presented in a modular fashion with summaries and tables. It is intended that one of the modules in the common technical document be reserved as a region-specific module.

The common technical document modular structure is envisioned as shown in the graphic at the end of this document and includes the following:

Components		
Module I	Regional Administrative Information	(*not part of Common Technical Document*)
Module II	IIA Executive Summaries	Quality (pending) Nonclinical (provided) Clinical (pending)
	IIB Nonclinical Summaries	IIB1 Written Summary (provided) IIB2 Tabulated Summary (provided)
	IIC Clinical Summaries, comprising written and tabulated summaries	(pending)
Module III	Quality	(provided—nine attachments pending)
Module IV	Nonclinical Data Study Reports	(provided)
Module V	Clinical Data Study Reports	(provided)

III. Components Being Made Available at This Time

In addition to the preamble to the draft guidance entitled ''M4 Common Technical Document,'' and an organizational graphic, the following components are being made available in the docket and on the Internet at this time:

1. Module IIA—Nonclinical Executive Summary;
2. Module IIB—Nonclinical Written and Tabulated Summaries;
3. Module III—Quality table of contents and explanatory notes (nine attachments still pending);
4. Module IV—Nonclinical Data Study Reports table of contents and explanatory notes; and
5. Module V—Clinical Data Study Reports table of contents and explanatory notes.

These components detail the tables of contents for Modules III, IV, and V accompanied by explanatory notes. Module III will be supplemented further by a series of nine detailed attachments, which may be available in summer of 2000. (The exact content of Module III may evolve as the Expert Working

Group's discussions progress.) Modules IIA Clinical and Quality and IIC should also be available for consultation in summer 2000. Module IIA/B Nonclinical is being made available at this time.

The ICH Steering Committee and Expert Working Groups are requesting comments on the components being made available by this notice. Once all the components of the draft guidance entitled ''M4 Common Technical Document'' are ready, a compiled text will be released to complete step 2 of the ICH process. It is anticipated that this will occur in summer 2000.

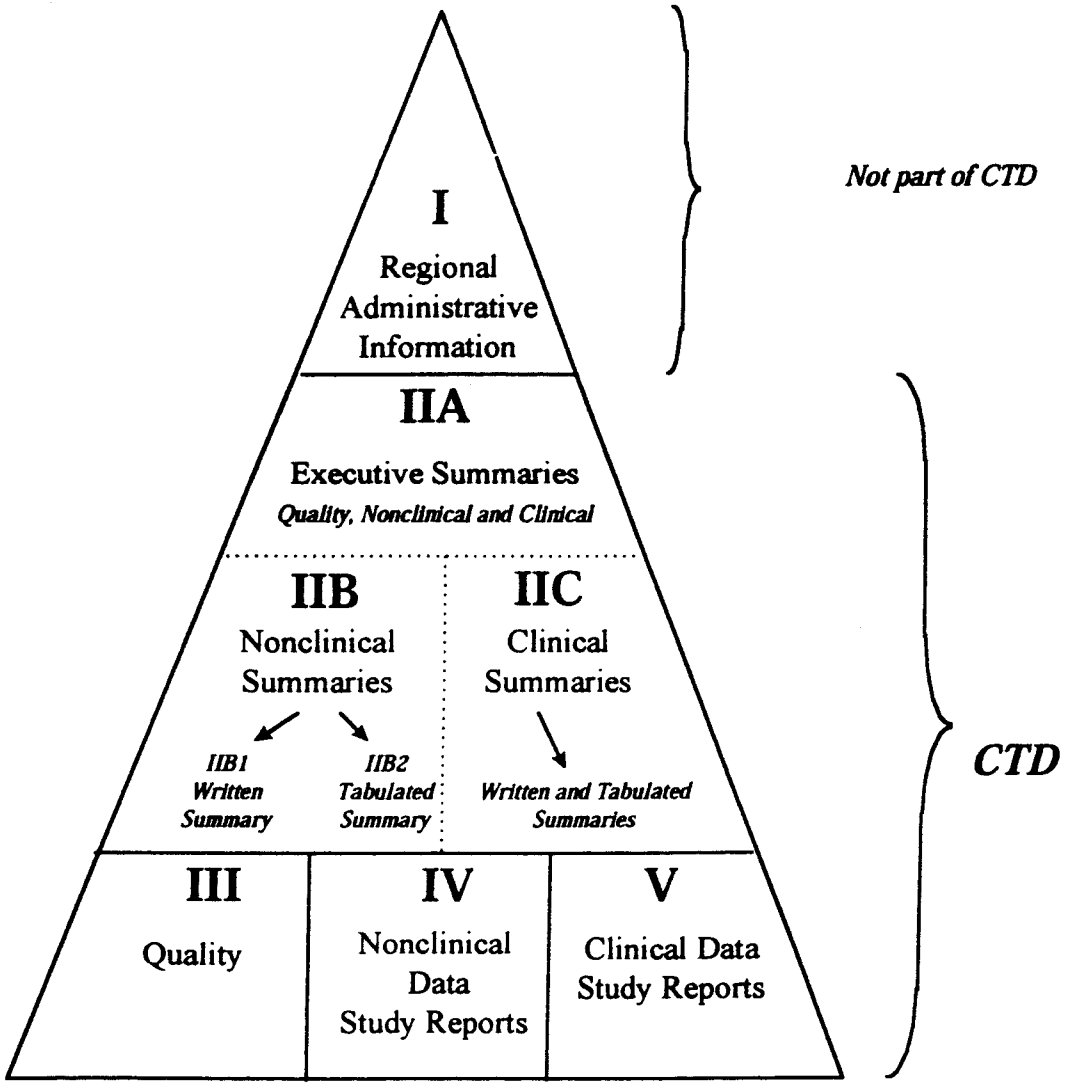
These components of the draft guidance represent the agency's current thinking on the content and format of a common application for designated new products (i.e., the common technical document). These components do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

IV. Comments

Interested persons may, on or before March 13, 2000, submit to the Dockets Management Branch (address above) written comments on these components of the draft 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. The components of the draft guidance, made available by this notice, and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

BILLING CODE 4160–01–F

Diagram 1: Diagrammatic Representation of the ICH Common Technical Document



Dated: February 8, 2000.

Margaret Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3343 Filed 2–9–00; 11:32 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0053]

Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme;'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.'' These draft guidance documents are neither final, nor are they in effect at this time. The review prioritization scheme guidance document sets forth factors FDA (we) would consider in categorizing a reprocessed single-use device (SUD) as high, moderate, or low risk. The enforcement priorities guidance document sets forth our priorities for various requirements based on the risk categorization of a device.

DATES: Submit written comments concerning either guidance by April 11, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies (on a 3.5 diskette) of the guidance documents entitled ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme'' and ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax