TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1190
361.1(d)(8)		50	6.8	340	0.1	34
Total						1304

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Forms	No. of Recordkeepers	Annual Frequency per Recordkeeping	Hours per Record-Keeper	Total Hours
361.1(c)(2)		80	1 per qtr = 4 per year	10	800
361.1(d)(5)		50	6.8	0.75	38
Total					838

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16824 Filed 7–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0582]

Guidance for Industry on Available Therapy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Available Therapy.'' The document is intended to provide guidance to industry on the meaning of the term ''available therapy'' as used by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drug products: Janet Jones, Center for Drug Evaluation and Research (HFD–040), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5445.

For information regarding biological products: Robert Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1148, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Available Therapy.'' The term ''available therapy'' and related terms, such as ''existing treatments'' and ''existing therapy,'' appear in a number of regulations and policy statements issued by CDER and CBER, but these terms have never been formally defined by the agency. Some confusion has arisen about, for example, whether ''available therapy'' refers only to products approved by FDA for the use in question, or whether the term could also refer to products used off-label or to treatments not regulated by FDA, such as surgery. The guidance document is intended to inform the public of the agency's interpretation of the term ''available therapy.''

In the **Federal Register** of February 7, 2002 (67 FR 5831), FDA announced the availability of a draft guidance entitled ''Available Therapy.'' The document provided interested persons an opportunity to submit comments by April 8, 2002. On October 17, 2002, the United States District Court for the District of Columbia invalidated the ''Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients'' (the pediatric rule) and enjoined FDA from enforcing the rule. (See *Association of Am. Physicians and Surgeons, Inc.* v. *United States Food and Drug Admin.*, 2002 U.S. Dist. LEXIS 19689 (Oct. 17, 2002).) As a result, FDA has deleted all references to the pediatric rule in the guidance.

In addition, FDA has revised the definition of ''available therapy.'' The revised definition seeks to resolve issues raised in comments requesting clarification of the proposed definition and confusion about situations where the only available therapy has been approved under the accelerated approval regulations (21 CFR 314.500 and 601.40). The term ''available therapy'' has been revised to explain

that the existence of a therapy already approved under the accelerated approval regulations will not necessarily preclude additional therapies for the same specific indication from being approved under the accelerated approval regulations or designated for the Fast Track drug development programs.

The revisions to the definition of ''available therapy'' affect FDA's Fast Track drug development programs. As a result, FDA has similarly revised its guidance for industry on Fast Track Drug Development Programs—Designation, Development and Application Review to discuss situations where the only available therapy is approved under the accelerated approval regulations.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Two copies of any mailed 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 guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/guidelines.htm*.

Dated: July 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16761 Filed 7–22–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0281]

Medical Devices: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Final Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised final guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' This revised guidance extends by 1 year a voluntary pilot premarket review program that may reduce the burden on manufacturers who face conflicting premarket submission format and content requirements in different countries. The pilot program is intended to evaluate the utility of an alternative submission procedure as described in the document entitled ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices'' (draft STED document). The draft STED document was developed by Study Group 1 (SG1) of the Global Harmonization Task Force (GHTF) and issued as a working draft in December 2000. The GHTF is a voluntary group comprised of medical device regulatory officials and industry representatives from the United States, Canada, Australia, the European Union, and Japan. Each of these member countries will participate in the pilot program and will provide specific directions for implementing the program within their respective jurisdictions.

DATES: Submit written comments at any time. The pilot program is extended until June 25, 2005.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff'' 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 your request to 301–443–8818.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/opacom/backgrounder/voice.html*. Comments are to be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4879, e-mail: *hrs@cdrh.fda.gov*; or Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, e-mail: *ejr@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 26, 2003 (68 FR 38068), FDA announced the availability of a guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' The guidance document announced a pilot premarket review program and solicited participation from the medical device industry. The pilot program is intended to evaluate the utility of an alternative submission procedure as described in the draft STED document prepared by SG1 of the GHTF. The document seeks to harmonize the different requirements for premarket submissions in various countries.

The June 26, 2003, guidance and notice of availability announced that the pilot program would be in effect for 1 year from the date of publication of the notice of availability. In this revised guidance, FDA is extending the pilot program for 1 more year. Other than updated contact information, there are no other changes to the guidance document. FDA received no comments on the guidance document. The revised guidance is a level 2 guidance under FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). As such, FDA made the guidance available on its Web site on July 6, 2004.

The GHTF is a voluntary group comprised of medical device regulatory officials and industry representatives from the United States, Canada, Australia, the European Union, and Japan. The goals of the GHTF include