B. 510(k) Reviews Conducted by Accredited Third Parties

In the 18 months under the third-party review pilot program, FDA received only 22 total 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time as the pilot program, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 2001. The agency has experienced that the number of 510(k)s submitted by accredited persons for third-party review since the last OMB approval in 2001 has been approximately 210 annually, which is 14 annual reviews per each of the estimated 15 accredited reviewers.

1. Premarket Reports

Under this program, EU CABs will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered since this collection was last reviewed in 2001, the agency has experienced that nine European manufacturers have not received any third-party requests for review annually. The agency estimates, based on dialog with EU officials and actual experience, nine firms will be designated to act as EU CABs.

2. Quality System Reports

Under this program, EU CABs will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./E.C. MRA and actual experience since the collection was last approved by OMB in 2001, the agency anticipates that European manufacturers will request third-party audits for approximately 36 medical device products annually. The agency estimates that nine EU CABs will perform these evaluations.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 210 annual submissions of 510(k)s for third-party review.

As stated previously, firms designated as EU CABs will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such review will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each review. The agency anticipates that 45 premarket reports and 36 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–109 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0377 and 2004D–0378]

International Conference on Harmonisation; Draft Guidances on E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs and S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals; Availability; Reopening of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 18, 2005, the comment periods for the draft guidances entitled ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' and ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals.'' The draft guidances were prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. FDA published notices of availability of the draft guidances in the **Federal Register** of September 13, 2004 (69 FR 55163 and 69 FR 55164, respectively). FDA is taking this action in response to requests to extend the comment periods for both draft guidances.

DATES: Submit written or electronic comments on the draft guidances by February 18, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidances 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.* Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidances.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance entitled ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'': Douglas C. Throckmorton, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane,Rockville MD, 20857, 301–594–5400.

Regarding the guidance entitled ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'': John Koerner, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5338.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2004, FDA announced the availability of the following two draft guidances prepared under the auspices of the ICH:

• ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' (69 FR 55163; Docket No. 2004D–0377) provides recommendations to sponsors concerning clinical studies to assess the potential of a new drug to cause cardiac arrhythmias, focusing on the assessment of changes in the QT/QTc interval on the electrocardiogram as a predictor of risk.

• ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'' (69 FR 55164; Docket No. 2004D–0378) describes a nonclinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization and includes information concerning nonclinical assays and an integrated risk assessment.

Interested persons were given until December 13, 2004, to submit comments on the draft guidances.

On December 13, 2004, FDA received letters from Wyeth Pharmaceuticals requesting that the agency extend the comment periods for the draft guidances.

In response to these requests, FDA has decided to reopen the comment period on the draft guidances until February 18, 2005, to allow the public more time to review and comment on the contents.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances on or before February 18, 2005. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the corresponding docket number of the draft guidance as follows: Docket No. 2004D–0377 ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' and Docket No. 2004D–0378 ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals.'' The draft guidances 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 draft guidance documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: December 28, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–110 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0046]

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

DATES: We welcome general comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments 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*. We have provided information in the tables in the **SUPPLEMENTARY INFORMATION** section of this document on where to obtain a single copy of any of the guidance documents listed.

FOR FURTHER INFORMATION CONTACT: *Regarding GGPs*: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's GGPs were published in the **Federal Register** of September 19, 2000 (65 FR 56468), and became effective October 19, 2000. GGPs are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance (§ 10.115 (21 CFR 10.115)). In § 10.115(n)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that published October 24, 2001 (66 FR 53836).

The following comprehensive list identifies all guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn since the last publication of this comprehensive list are also identified. These withdrawn guidances include some final and draft guidances that had been withdrawn prior to the date of publication of this list, and some that are being withdrawn as of this date. In accordance with the agency's general policy on guidances, you may comment on this list and on any FDA guidance document at any time. Please note that although we have stated that the ''Guidance for Industry on Qualified Health Claims in Labeling of Conventional Foods and Dietary Supplements'' (December 2002) has been ''replaced'' by subsequent guidance, the agency has not abandoned the position in the 2002 guidance regarding reasonable consumer standard.

We have organized the documents by the issuing center or office within FDA, and have identified the pertinent intended users or regulatory activities. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing center or office maintains its own database, there are slight variations in the way in which they provide information in the tables in this document.

The following most frequently used Internet sites for agency guidances are provided for future reference:

• Center for Biologics Evaluation and Research (CBER): *http://www.fda.gov/cber/guidelines.htm*

• Center for Drug Evaluation and Research (CDER): *http://www.fda.gov/cder/guidance/index.htm*

• Center for Devices and Radiological Health (CDRH): *http://www.fda.gov/cdrh/guidance.html*

• Center for Food Safety and Applied Nutrition (CFSAN): *http://www.cfsan.fda.gov/dms/guidance.html*

• Center for Veterinary Medicine (CVM): *http://www.fda.gov/cvm/guidance/published.htm*

• Office of Regulatory Affairs (ORA) and Office of the Commissioner: *http:/*