existing paperwork clearance for the rule.[2]

Deceptive lending cases at the FTC and elsewhere suggest that consumers who do not understand the terms of their mortgages can be subject to deception, that deception can occur even when consumers receive the disclosures required by the Truth-in-Lending Act, 15 U.S.C. 1601 *et seq.* (TILA), and that deception about mortgage terms can result in substantial consumer injury.

Despite a long history of mortgage disclosure requirements and many legislative and regulatory proposals regarding disclosures, little empirical evidence exists to document the effect of current disclosures on consumer understanding of mortgage terms, consumer mortgage shopping behavior, or consumer mortgage choice.

The Mortgage Disclosure Study will examine: (1) How consumers search for and choose mortgages; (2) how consumers use and understand information about mortgages, including required disclosures; and (3) whether improved disclosures might improve consumer understanding, consumer mortgage shopping, and consumers' ability to avoid deception. The research also may assist the targeting of the FTC's enforcement actions by identifying areas most prone to consumer misunderstanding and lender deception and may help refine disclosure remedies imposed on deceptive lenders.

1. Description of the Collection of Information and Proposed Use

The FTC is conducting this study in two phases: (1) A qualitative research phase; and (2) a quantitative research phase. The qualitative research phase includes two focus groups and 36 in-depth interviews. The quantitative research will include copy tests of current and alternative disclosures. Results from the first phase will be used to refine the design of the second phase.

The two focus groups and 25 of the in-depth interviews have been completed under the current PRA clearance and are not part of this extension request.[3] Eleven of the in-depth interviews have not yet been conducted. Accordingly, this extension request covers information collection for the 11 in-depth interviews that remain for the qualitative phase and the copy tests for the quantitative phase.

The remaining in-depth interviews will be conducted with 11 consumers who have recently completed a mortgage transaction. Respondents will be asked to bring their loan documents to the interview. Some of the interviews will be with consumers who obtained their mortgage from a prime lender and some will be with consumers who obtained their mortgage from a subprime lender. The purpose of the interviews is to gain in-depth knowledge of the extent to which consumers use, search for, and understand mortgage information—including information about their own recent loans.

The quantitative research phase will consist of copy test interviews of 800 consumers who entered into a mortgage transaction within the previous two years. If possible, approximately half of the respondents will be consumers who obtained their mortgage from a prime lender and half will be consumers who obtained their mortgage from a subprime lender. The purpose of the copy tests will be to examine whether alternative disclosures can improve consumer understanding of mortgage terms and help to reduce potential deception about mortgage offers. The findings from the focus groups and in-depth interviews will be used to refine the alternative disclosures used in the copy tests.

All information will be collected on a voluntary basis. The FTC has contracted with two consumer research firms (one each for the qualitative and quantitative phases) to recruit respondents, conduct the interviews, and write a brief methodological report. The results will assist the FTC in determining how required disclosures and other information affect consumers' ability to understand the cost and features of mortgages. This understanding will further the FTC's mission of protecting consumers and competition in this important market.

2. Estimated Hours Burden

Qualitative Research

The qualitative phase is complete except for 11 in-depth interviews. If all respondents for those interviews are single decision makers, this would amount to an 11 hour burden. However, some of the interviews may include couples. Assuming that about half of the interviews include couples, the hours burden for the in-depth interviews would increase to 17 hours ((6 × 2 hours) + (5 × 1 hour)).

Quantitative Research

Approximately 800 consumers who engaged in a mortgage transaction during the previous two years will participate in the quantitative phase of the research. Each copy test interview will take roughly 20–30 minutes. The estimated hours burden for the quantitative phase ranges from 267 hours (800 respondents × ⅓ hour per respondent) to 400 hours (800 respondents × ½ hour per respondent).

Total

The total estimated hours burden for both phases of the study ranges from 278 hours (11 hours + 267 hours) to 417 hours (17 hours + 400 hours).

William E. Kovacic,

General Counsel.

[FR Doc. 05–176 Filed 1–4–05; 8:45 am]

BILLING CODE 6750–01–P

[2] In its September 28, 2004 Federal Register Notice, the FTC indicated it was seeking to extend the current PRA clearance through December 31, 2005. The FTC staff expect the consumer research for the Mortgage Disclosure Survey to be completed by that date, but is now seeking to extend the current PRA clearance through December 31, 2006, to allow for any unanticipated delays.

[3] The September 28, 2004 Federal Register Notice included all of the in-depth interviews in the extension request; 25 of those interviews were subsequently completed under the current clearance and are not a part of this extension request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0437]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 4, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and

Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Third-Party Review Under FDAMA, Third-Party Premarket Submission Review, and Quality System Inspections Under U.S./E.C. Mutual Recognition Agreement (OMB Control Number 0910–0378)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's submission under section 510(k) of the act (21 U.S.C. 360(k)) for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low-to-moderate risk devices.

The third-party program under the U.S/European Community (E.C.) Mutual Recognition Agreement (MRA) is intended to implement that part of the U.S./E.C. MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. conformity assessment body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type evaluations and verifications for selected devices based on European Union (EU) requirements under the voluntary third-party program authorized by MRA. Firms designated as EU CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA's requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EU CABs to FDA. The EU CABs would also be required to maintain copies of their evaluation reports for a period of no less than 3 years.

In the **Federal Register** of October 14, 2004 (69 FR 61021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	15	1	15	24	360
510(k) reviews conducted by accredited third parties	15	14	210	40	8,400
Premarket reports by EU CABs	9	5	45	40	1,800
Quality system reports by EU CABs	9	4	36	32	1,152
Total					11,712

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

TABLE 2.–ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Record-keepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record-keeper	Total Hours
510(k) reviews	15	14	210	10	2,100
Premarket reports by EU CABs	9	5	45	10	450
Quality system reports by EU CABs	9	4	36	10	360
Total					2,910

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

The burdens are explained as follows:

I. Reporting

A. Requests for Accreditation

Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. In the past 3 years, however, the agency has averaged receipt of 15 applications for recognition of third-party review accredited persons, and 9 EU CABS. The agency has accredited 15 of the applicants to conduct third-party reviews, and 9 EU CABs.

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: