Item No.	Bureau	Subject
1	WIRELINE COMPETITION.	TITLE: High-cost Universal Service Support (WC Docket No. 05–337); Federal-State Joint Board on Universal Service (CC Docket No. 96–45); Lifeline and Link Up (WC Docket No. 03–109); Universal Service Contribution Methodology (WC Docket No. 06–122); Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities (CG Docket No. 03–123); Implementation of the Local Competition Provisions in the Telecommunications Act of 1996 (CC Docket No. 96–98); Developing a Unified Intercarrier Compensation Regime (CC Docket No. 01–92); Intercarrier Compensation for ISP-Bound Traffic (CC Docket No. 99–68); and IP-Enabled Services (WC Docket No. 04–36). SUMMARY: The Commission will consider a Report and Order, Order on Remand, and Further Notice of Proposed Rulemaking addressing the comprehensive reform of intercarrier compensation and universal service.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–26740 Filed 11–6–08; 11:15 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 5, 2008.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. CapitalSource Inc., CapitalSource Finance LLC, and CapitalSource TRS Inc., all of Chevy Chase, Maryland, to become bank holding companies by acquiring 100 percent of the voting shares of CapitalSource Bank, Los Angeles, California.

Board of Governors of the Federal Reserve System, November 5, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–26690 Filed 11–7–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0375] (formerly Docket No. 2004D–0555)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff; ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300''

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 (the PRA).

DATES: Fax written comments on the collection of information by December 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3793.

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.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—(OMB Control Number 0910–NEW)

Under the Medical Device Amendments of 1976 (Public Law 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance.

Condoms without spermicidal lubricant containing nonoxynol-9 are classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Public Law 101–629) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000, Congress enacted Public Law 106–554, which among other provisions, directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases* * *.'' FDA is recommending labeling changes intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA believes that this is a one-time burden, because once a label is redesigned, it can be used indefinitely.

In the **Federal Register** of November 14, 2005 (70 FR 69156), FDA published a 60-day notice soliciting public comment on the information collection provisions, contained in the draft special controls guidance document then entitled ''Labeling for Male Condoms Made of Natural Rubber Latex.'' FDA has subsequently retitled the special controls guidance document containing these information collection provisions to avoid confusion between the guidance established as a special control for condoms classified under 21 CFR 884.5300 by the final rule published elsewhere in this issue of the **Federal Register** and the November 2005 draft guidance, which remains available (but not for implementation) in conjunction with the pending proposal to amend another classification. No comments were received on the information collection provisions in response to the 60-day notice.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
35[2]	34	1,190	12	14,280
3[3]	34	102	12	1,224
Total				15,504

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Current manufacturers for year one.
[3] New Manufacturers for years two and three.

The reporting burden hours to respondents in the first year is a one-time burden of 14,280 hours. FDA expects three new manufacturers or repackagers to enter the market yearly, and collectively have a one-time burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to redesign the labeling for OTC drugs is an appropriate proxy for the estimated burden to redesign condom labeling. Cost estimates were adjusted to account for inflation using the producer price index.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807 subpart E have been approved under OMB control no. 0910–0120; the collections of information under 21 CFR part 820 have been approved under OMB control no. 0910–0073; and the collections of information in part 801 (21 CFR part 801) have been approved under OMB control no. 0910–0485.

The collection of information under § 801.437 does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26828 Filed 11–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0093]

Determination of Regulatory Review Period for Purposes of Patent Extension; IXEMPRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IXEMPRA 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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