Internet Protection Act—Universal Service for Schools and Libraries.

Form No.: FCC Forms 479, 486 and 500.

Type of Review: Revision of a currently approved collection.

Respondents: Not-for-profit institutions, and businesses or other for-profit.

Number of Respondents: 40,000.

Estimated Time Per Response: 15.37 hours per response (avg.).

Frequency of Response: Recordkeeping and reporting requirements, and third party disclosure requirement.

Total Annual Burden: 75,000 hours.

Total Annual Cost: N/A.

Needs and Uses: Section 1271 and related sections of the Children's Internet Protection Act (CIPA) provide that in order to be eligible under section 254 of the Communications Act of 1934, as amended (the Act), to receive discounted Internet access, Internet services, and internal connection services, schools and libraries that have computers with Internet access must have in place certain Internet safety policies. FCC Forms 479, 486 and 500 are used to implement the requirements of CIPA and section 254.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–28770 Filed 11–16–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Notice

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 66 FR 56676, November 9, 2001.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 A.M., Wednesday, November 14, 2001.

CHANGE OF MEETING DATE: Notice is hereby given that the Board of Directors meeting scheduled for November 14, 2001 has been changed to Wednesday, November 28, 2001 at 10 a.m.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

James L. Bothwell,

Managing Director.

[FR Doc. 01–28921 Filed 11–15–01; 11:09 am]

BILLING CODE 6725–01–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 application 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 13, 2001.

A. Federal Reserve Bank of Cleveland (Stephen J. Ong, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. Wesbanco, Inc., Wheeling, West Virginia; to merge with American Bancorporation, Wheeling, West Virginia, and thereby indirectly acquire Wheeling National Bank, St. Clairsville, Ohio. Comments on this application must be received by December 10, 2001.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Central Texas Bankshare Holdings, Inc., Columbus, Texas, and Colorado County Investment Holdings, Inc., Wilmington, Delaware; to acquire 45.33 percent of the voting shares of Hill Bancshares Holdings, Inc., Weimar, Texas, and thereby indirectly acquire voting shares of Hill Bancshares, Inc., Wilmington, Delaware, and Hill Bank & Trust Company, Weimar, Texas.

Board of Governors of the Federal Reserve System, November 13, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–28816 Filed 11–16–01; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0450]

Prescription Drug User Fee Act (PDUFA); Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the Prescription Drug User Fee Act (PDUFA). The legislative authority for PDUFA expires at the end of September 2002, and without further legislation the fees and resources provided under PDUFA will also expire. FDA is now evaluating the PDUFA provisions. The Federal Food, Drug, and Cosmetic Act (the act) encourages FDA to consult with stakeholders, as appropriate, in carrying out agency responsibilities. Accordingly, FDA will convene a public meeting to hear stakeholder views on this subject. FDA is proposing three specific questions, and the agency is interested in responses to these questions and any other pertinent information stakeholders would like to share.

Date and Time: The public meeting will be held on Friday, December 7, 2001, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by November 30, 2001. Submit written or electronic comments by January 25, 2002.

Location: The public meeting will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

For information regarding this notice contact: Patricia A. Alexander, Office of Consumer Affairs, Office of Communications and Constituent Relations (HFE–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4391, FAX 301–827–3052, e-mail: palexand@oc.fda.gov.

For registration information contact: Carole A. Williams, Office of Consumer Affairs, Office of Communications and

Constituent Relations (HFE–40), Food and Drug Administration, Rockville, MD 20857, 301–827–4394, FAX 301–827–2866, e-mail: pubmtg@oc.fda.gov. All registration materials should be sent to Carole A. Williams. Electronic registration for this meeting is available at: http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdockets.cfm. Registrations will be accepted on a first-come, first-served basis. Individuals who register to make an oral presentation will be notified of the scheduled time for their presentation prior to the meeting. All participants are encouraged to attend the entire day.

Registration and Requests for Oral Presentation: To register to attend the meeting, submit your name, title, business affiliation, address, telephone, fax number, and e-mail address. If you wish to make an oral presentation during the open public comment period of the meeting, you must specify on your registration you wish to make a presentation. You must submit the following: (1) A written statement for each question addressed, (2) the names and addresses of all who plan to participate, (3) the approximate time requested to make your presentation. Depending on the number of presentations, FDA may have to limit the time allotted for each presentation. Presenters must submit two copies of each presentation given. If you need special accommodations due to a disability, please inform the registration contact person when you register.

SUPPLEMENTARY INFORMATION:

I. Background

A. September 2000 Public Meeting

On September 15, 2000, FDA held a public meeting to discuss the future of PDUFA and to listen to the views of all interested constituents. This public meeting was held as the agency began to prepare for new or amended authorizing legislation. At that meeting, the agency learned more about the expectations and concerns of various constituent groups and citizens regarding the PDUFA program. The December 7, 2001, meeting will continue this dialogue.

B. PDUFA I and PDUFA II

In 1992, Congress passed PDUFA authorizing FDA to collect fees from companies that produce certain human drug and biological products. The original PDUFA (PDUFA I) had a 5-year sunset. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA). Part of FDAMA included an extension of PDUFA (PDUFA II) for an additional 5 years. PDUFA's original intent was to provide FDA with additional revenue so it could hire more reviewers and support staff and upgrade its information technology to speed up the application review process for human drug and biological products without compromising review quality.

C. Authority to Collect Fees

The revenues are provided by a set of three fees, with one-third of the total annual revenue coming from each of the following fees: (1) Application fees for the submission of certain human drug or biological applications (in fiscal year (FY) 2001, $309,647 per application with clinical data, and $154,823 per application without clinical data or per supplemental application with clinical data); (2) annual establishment fees paid for each establishment that manufactures certain prescription drugs or biologicals (in FY 2001, $145,989 per establishment); and (3) annual product fees assessed on certain prescription drug and biological products (in FY 2001, $21,892 per product). In the aggregate, these fees are expected to generate $135 million in FY 2002. (This is a downward adjustment-previously they had been expected to generate about $162 million). No separate fees are charged for investigational new drug applications (INDs). However, since the review of investigational new drug applications is included in the process for the review of human drug applications, as defined in PDUFA, FDA uses some of the application, establishment, and product fees collected for the review of INDs.

D. Review Performance Goals

In 1992, FDA agreed to meet a set of review performance goals that became more stringent each year, if FDA also received sufficient fee resources to enable goal achievement. These goals applied to the review of original new human drug and biological applications, resubmissions of original applications, and supplements to approved applications. FDA met every PDUFA I performance goal.

Under PDUFA II, the review goals continue to shorten. By 2002, the PDUFA II goals call for FDA to review and act on 90 percent of the following: (1) Standard new drug and biological product applications and efficacy supplements within 10 months; (2) priority new drug and biological product applications and efficacy supplements (i.e., for products providing significant therapeutic gains) within 6 months; (3) manufacturing supplements within 6 months, and those requiring prior approval within 4 months; (4) class 1 resubmissions within 2 months, and class 2 resubmissions within 6 months.

In addition, PDUFA II added a new set of goals intended to improve FDA's responsiveness to, and communication with, industry sponsors during the early years of drug development. These goals specify timeframes for activities such as scheduling meetings and responding to various sponsor requests.

E. Impact on Drug Review Process

While PDUFA's original intent was to speed up the review process, PDUFA II's intent is to speed up the entire drug development process. By providing an influx of needed resources, PDUFA has had a dramatic and undeniable impact on the drug review process. Total resources for drug review activities have increased from $120 million in 1992, before PDUFA was enacted, to an estimated $329 million in FY 2002, a little more than half of which will come from fees paid by industry. These resources allowed FDA to increase its drug and biological review staff by almost 60 percent between 1993 and 1997, adding about 660 staff-years to the program by 1997. By the end of PDUFA II in 2002, FDA expects to have added another 340 staff-years of effort to this program. These additional staff, and resources to support them, have enabled FDA to respond more rapidly to new drug and biologic applications without compromising review quality.

While it is important to note that PDUFA's goals specify decision times, not approval times, both decision and approval times have decreased dramatically. Total approval time, the time from the initial submission of a marketing application to the issuance of an approval letter, has dropped from a pre-PDUFA median of 23 months to an estimated 15 months in 2001. Total approval time for priority applications, those for products providing significant therapeutic gains, has dropped from a median of over 12 months in the early PDUFA years to 6 months. In addition, because FDA has put greater effort into communicating what it expects applicants to submit, a higher percentage of applications are being approved. Before PDUFA, only about 60 percent of the applications submitted were ultimately approved. Now, about 80 percent are approved. For the consumer, this has meant more products available more quickly.

F. Challenges

Notwithstanding these successes, the agency has encountered challenges in trying to meet the PDUFA II goals.

Assuring that enough appropriated funds are spent on the process for the review of human drug applications to meet requirements of PDUFA, and at the same time spending our resources in a way that best protects the health and safety of the American people, is becoming increasingly difficult. Each year, the amount that FDA must spend from appropriations on the drug review process is increased by an inflation factor. Yet, since 1992, FDA has not received increased appropriations to cover the costs of the across-the-board pay increases that must be given to all employees. The result is that our workforce and real resources for most programs other than PDUFA have contracted each year since 1992 while we struggle to ensure that enough funds are spent on the drug review process to meet this PDUFA requirement. FDA will be unable to continue to reduce staffing levels in FDA programs other than drug review and still maintain those programs in a way that best protects and promotes the public health and merits public confidence.

Another challenge we have faced in PDUFA II is that we underestimated the resources we would need to meet the new, demanding PDUFA II goals. In addition, the fees we have collected have been significantly less than expected. Revenues have been lower than projected due to the reduced number of fee-paying applications and the increased number of fee-waived applications. This has also resulted in lower than expected fee revenues from products and establishments. In FY 2001, about 30 percent of applications received fee waivers. FDA will need to spend all of the reserve funds available in order to try to continue to meet PDUFA goals. FDA anticipates that by the end of PDUFA II the agency will have depleted all fee reserves.

Despite this fluctuation in revenues, our workload under PDUFA II continued to rise. Many of the activities covered by PDUFA II performance goals do not, themselves, generate fees, yet the workload in these areas has been substantial. For example, the numbers of commercial INDs, efficacy supplements, and manufacturing supplements are up, and the number of meetings, responses to clinical holds and special protocol assessments, all of which have specific PDUFA II performance goals, have been higher than anticipated. The new pediatric and fast track provisions of FDAMA, none of which received specific additional funding, also have contributed significantly to this increased workload.

FDA is also concerned about the safety of new drugs and biologics following approval and marketing. FDA's postmarket monitoring activities are not currently funded by PDUFA. More rigorous safety monitoring of newly approved drugs in the first few years after a product is on the market could help to detect unanticipated problems earlier. The current system for detecting adverse drug and biologics events does not provide sufficient data on the actual incidence of problems. Another concern is the growth in prescription drug advertising. Current PDUFA funding does not cover the agency's cost of reviewing promotional materials (over 37,000 pieces in 2000).

Although FDA has been able to meet most of its performance goals despite these challenges, we do not believe this will continue in the future. We do not foresee increasing or even maintaining performance levels until resources are available to meet the increased workload. These resources can be provided either from appropriated dollars or from user fees. However, to date we have not seen increases in appropriated dollars needed to meet the shortfalls we have experienced.

We may, in fact, be seeing that our efforts to meet the new PDUFA II goals have led to an unintended consequence regarding approval times of standard new drug and biologics applications. These approval times have begun to increase because more applications require multiple review cycles to reach approval. We believe this may be due to the fact that reviewers, pressed to meet the new PDUFA II goals for drug development (e.g., meetings, special protocol assessments, and responses to clinical holds), have had less time to devote to resolving last minute problems with these standard applications in time to meet the action goal date. As a result, the application must undergo an additional review cycle with its attendant timeframes and goals. Our statistics on this trend are preliminary and we are watching it closely. However, if our user fee program is to continue, it must be on a sound financial footing and based on reliable estimates of workload and resources.

II. Scope of Discussion

The legislative authority for PDUFA II expires at the end of September 2002. Without further legislation the fees and resources it has provided will also expire. Public input is important at this time as final preparations are being made to propose reauthorization. Section 903(b) of the act (21 U.S.C. 393(b)) encourages FDA to consult with stakeholders, as appropriate, in carrying out agency responsibilities. Accordingly, FDA will convene a public meeting on December 7, 2001. Interested persons are invited to attend and present their views. A list of questions that we are asking interested parties to address at this meeting follows:

1. Has PDUFA supported FDA's mission to protect and promote public health? What should be retained or changed to enhance the program?

2. Should PDUFA allow the use of user fee funding to monitor safety after new drug or biologic approval?

3. How can FDA ensure that PDUFA goals are met if there continues to be a funding shortfall? If the funding shortfall persists, should FDA, in order to best protect and promote the public health, set review priorities and, if so, how? Should there be flexibility in setting user fees to cover the increased cost of the program?

III. Comments

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on or before January 25, 2002. Submit electronic comments to fdadockets@oc.fda.gov or http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. You should annotate and organize your comments to identify the specific questions to which they refer. (See above.) You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document. You may review received comments approximately 15 days after the meeting in the Dockets Management Branch, Monday through Friday between 9 a.m. and 4 p.m. or on the Internet at http://www.fda.gov/oc/pdufa/meeting2001/.

IV. Transcripts

You may request a copy of the transcript in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the meeting at a cost of 10 cents per page. You may also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Dockets Management Branch or on the Internet at http://www.fda.gov/oc/pdufa/meeting2001/.

V. Electronic Access

Persons with access to the Internet may obtain more information about PDUFA at http://www.fda.gov/oc/pdufa/default.htm.

Dated: November 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29002 Filed 11–15–01; 4:39 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of actions under the NIH Guidelines for research involving recombinant DNA molecules (NIH Guidelines) and request for comment on the information collection provisions under the Paperwork Reduction Act of 1995.

SUMMARY: The actions described in this Notice amend the NIH Guidelines to enhance oversight of human gene transfer research by modifying the requirements for the reporting and analysis of serious adverse events in human gene transfer research studies governed by the NIH Guidelines.

The first action modifies the scope of serious adverse events that are reportable on an expedited basis. Expedited reporting will now be required for those serious adverse events that are unexpected and associated with the use of the gene transfer product (i.e., there is a reasonable possibility that the experience may have been caused by the gene transfer product). The change also provides timeframes for expedited reporting and definitions of serious, associated, and unexpected adverse events. Under the amendments, summary information about other adverse events would be included in annual reports. Principal Investigators with multiple studies may submit a single annual report, provided that data are attributed to discrete sites. The annual reporting requirements are set forth in Appendix M–I–C–3 and the safety reporting requirements are in Appendix M–I–C–4. Those two sections have been submitted for OMB approval under the Paperwork Reduction Act of 1995 and this notice provides 30 days for public comment on those information collection requirements. Following this comment period, OMB analysis of the comments, and approval of the requirements, NIH OBA will publish a notice setting forth the effective date of Appendices M–I–C–3 and M–I–C–4.

The second action clarifies that, in accordance with applicable law and longstanding policy of the NIH Office of Biotechnology Activities (OBA), when information submitted in serious adverse event reports and annual reports is labeled trade secret or confidential commercial information, the NIH OBA will assess this claim and make a determination. If NIH OBA determines that the data so labeled are confidential commercial or trade secret and that their public disclosure would promote an understanding of key scientific or safety issues, the NIH OBA will seek agreement from the appropriate party to release such data.

The third action adds specific language to the NIH Guidelines to prohibit the submission of individually-identifiable patient information in serious adverse event and annual reports.

The fourth action is the establishment of a working group of the NIH Recombinant DNA Advisory Committee (RAC), to be known as the NIH Gene Transfer Safety Assessment Board (GTSAB), that will play a role in the analysis of safety information in gene transfer research studies. The working group will report safety information to the RAC and, thereby, disseminate it to the scientific and patient communities, as well as the general public.

In toto, these four changes will enhance the identification of significant safety issues across human gene transfer trials, increase public knowledge, and strengthen the protection of research participants in human gene transfer research studies. These changes are an important step toward harmonization of Federal safety reporting requirements. Additional efforts are underway within the Department of Health and Human Services to further enhance consistency in the collection of safety information and submission of safety reports, increase the quality of safety reports, and expedite review of critical safety information. NIH will continue to monitor and participate in these efforts, reevaluating and, as appropriate, changing the NIH Guidelines.

DATES: Comments on the information collection requirements in Appendix M–I–C–3 and Appendix M–I–C–4 must be submitted to the OMB at the address shown below by December 19, 2001. As information collection requirements, Appendix M–I–C–3 and Appendix M–I–C–4 will take effect upon OMB approval. All other provisions will take effect 30 days after November 19, 2001.

ADDRESSES: Comments should be sent to: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th Street, NW., Room 10235, Washington, DC 20503, Attn: Desk Officer for NIH.

FOR FURTHER INFORMATION: Background documentation and additional information can be obtained from the Office of Biotechnology Activities, National Institutes of Health, MSC 7985, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, Phone 301–496–9838, FAX 301–496–9839. The NIH OBA Web site is located at *http://www4.od.nih.gov/oba/*

SUPPLEMENTARY INFORMATION:

I. Background

This Action follows from a Proposed Action published in the December 12, 2000 **Federal Register** (65 FR 77655) and derives from an extensive process of deliberation and public consultation. It takes into account the reports of two specially convened NIH working groups as well as numerous written comments from the public on two separate proposals. The preponderant view emerging from this process supports the four main objectives of this Action, which are to: (1) Harmonize NIH requirements for expedited reporting of serious adverse events in gene transfer trials with those of FDA; (2) clarify how claims that annual and safety reports contain confidential commercial or trade secret information will be resolved, given the need for disclosure of information to ensure broad public knowledge of issues raised by gene transfer research; (3) maintain the privacy of individuals participating in gene transfer research; and (4) develop a new mechanism for the analysis and dissemination of adverse event information with the goal of enhancing knowledge about scientific and safety trends. The history leading up to each element of this Action is discussed below.

A. Scope and Timing of Serious Adverse Event Reports

A major purpose of this Action is to harmonize NIH requirements for the reporting of serious adverse events with those of the FDA. This harmonization is expected to enhance compliance with the NIH Guidelines. Significant non-compliance with the NIH Guidelines became evident in 1999 following the death of a participant in a human gene transfer research study. Subsequent to this event, the NIH OBA called on investigators conducting these studies to submit to the Office comprehensive pre-