the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 11, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–12914 Filed 5–14–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No: CB 98–03]

Announcement of the Availability of Financial Assistance and Request for Applications for Fiscal Year 1998 to Support Child Welfare Training Projects as Authorized by Section 426 of the Social Security Act, as Amended. 42 U.S.C. 626, CFDA: 93.648

AGENCY: Children's Bureau, Administration on Children, Youth and Families (ACF/DHHS).

ACTION: Notice of fiscal year 1998 Child Welfare Training Project priorities, availability of financial assistance, and request for applications to support Child Welfare Training Projects as authorized by section 426 of the Social Security Act, as Amended. 42 U.S.C. 626, CFDA: 93.648.

SUMMARY: The Children's Bureau, Administration on Children, Youth and Families, ACF, announces the availability of FY 1998 funds for competing new discretionary grants to public or other non-profit institutions of higher learning for special projects for training of personnel for work in the field of child welfare.

Federal funds for Child Welfare Training Project Priorities are available for: (1) professional education for public child welfare practitioners; (2) training for the frontline public child welfare agency staff in the use of the Statewide Automated Child Welfare Information Systems (SACWIS); and (3) training for child protective and child welfare services staff for collaboration with community-based agencies to provide services to at-risk families to prevent child abuse and neglect.

DEADLINE DATE: The closing time and date for the receipt of applications under this announcement is 4:30 p.m. (Eastern Time Zone), on July 20, 1998. Applications received after 4:30 p.m. of the closing date will be classified as late. Post marks and other similar documents DO NOT establish receipt of an application.

ADDRESSES: *Mailing and Delivery Instructions:* Mailed applications and applications delivered by overnight/express mail services shall be considered as meeting the announced deadline if they are received on or before the deadline receipt date, between the hours of 8:00 a.m. and 4:30 p.m. (Eastern Time Zone) and sent to the Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 415, Arlington, VA 22202. The telephone number is 1–800–351–2293. Any application received after the deadline time and date will not be considered for competition.

Hand Delivered Applications, Applicant Couriers: If applications hand delivered by applicants or applicant couriers are received on or before the deadline date between the hours of 8:00 a.m. and 4:30 p.m. (Eastern Time Zone) at the Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 415, Arlington, VA 22202, they shall be considered as meeting the announced deadline.

Electronic Transmissions: ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

Late Applications: Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of Deadlines: ACF may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc., or when there is a widespread disruption of the mail system. However, if ACF does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicants.

Program Announcement Requests: Copies of the program announcement may obtained by contacting the Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 415, Arlington, VA 22202. The telephone number is 1–800–351–2293. Copies of this announce will be automatically sent to all universities with accredited undergraduate and graduate social work programs. A copy of this program announcement is also located at the Children's Bureau website at http://www.acf.dhhs.gov/program/cb.

SUPPLEMENTARY INFORMATION: Grant awards of FY 1998 funds will be made by September 30, 1998. Under this announcement, approximately $2 million is available for the new awards. The announcement provides information regarding the funding level for each priority area. Applicants should note that the number of grants to be awarded under this program announcement are subject to the availability of funds.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) number of the Child Welfare Training Grants is 93.648.

Dated: May 11, 1998.

James A. Harrell,

Deputy Commissioner Administration on Children, Youth and Families.

[FR Doc. 98–12979 Filed 5–14–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0268]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision.

DATES: Submit written comments on the collection of information by July 14, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–

305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—Part 60 (21 CFR Part 60) (OMB control number 0910–0233—Extension)

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review, before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting 35 U.S.C. 156, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24, revision of the length of the regulatory review period, or may petition, under § 60.30, to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.'' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40, request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, five requests for revision of the regulatory review period have been submitted under § 60.24. One regulatory review period has been altered. No due diligence petitions have been submitted to FDA, under § 60.30, and consequently there have been no requests for hearings, under § 60.40, regarding the decisions on such petitions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	1	1	1	100	100
60.30	0	0	0	0	0
60.40	0	0	0	0	0

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

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12897 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0456]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction, Reporting and Recordkeeping Requirements,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 1997 (62 FR 62773), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0140. The approval expires on April 30, 2001.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12902 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0287]

Guidance for Industry on Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing; 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 ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This is revision 1 of the guidance. The guidance has been revised to reflect the recent availability of buspirone hydrochloride tablets in 15-milligram dosage forms. Bioequivalence is tested using the highest available dosage of the reference listed drug. The revised guidance also notes the nonlinearity of buspirone at multiple-dosing.

DATES: Written comments on agency guidance documents may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing'' to the Drug Information Branch (HFD–210), 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 this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sikta Pradhan, Center for Drug Evaluation and Research (HFD–652), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION: This guidance document is a level 2 guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on buspirone hydrochloride tablets in vivo bioequivalence and in vitro dissolution testing. 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 requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the guidance at any time to the Dockets Management Branch (address above). Two copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12903 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0276]

Guidance for Industry on Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements; 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 ''Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements.'' As required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act), this guidance for industry describes the standards for the prompt review of efficacy supplements. It also is intended to define those efficacy supplements that are eligible for priority review.

DATES: Written comments may be submitted on the guidance document by August 13, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration,