consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AGRYLIN (anagrelide), CLOLAR (clofarabine), and DIFLUCAN (fluconazole). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: March 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6332 Filed 3–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0317] (formerly Docket No. 03D–0317)

Guidance for Review Staff and Industry on Good Review Management Principles and Practices for Prescription Drug User Fee Act Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for review staff and industry entitled ''Good Review Management Principles and Practices for PDUFA Products.'' This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The guidance may also be obtained from CBER by mail by calling 1–800–835–4709, or 301–827–1800. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, suite 7215, 5515 Security Lane, Rockville, MD 20852, 301–594–3937; or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for review staff and industry entitled ''Good Review Management Principles and Practices for PDUFA Products.'' In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include providing guidance to industry and review staff in CDER and CBER on the good review management principles and practices (GRMPs) for the conduct of the first cycle review of a new drug application (NDA), a biologics license application (BLA), or an efficacy supplement under PDUFA.

The GRMPs in this guidance are based on the collective experience of CDER and CBER with review of applications for PDUFA products and are intended to promote efficient and consistent management of application reviews. The GRMPs also clarify roles and responsibilities of review staff in managing the review process and identify ways in which NDA and BLA applicants may further the effectiveness and efficiency of the review process.

In the **Federal Register** of July 28, 2003 (68 FR 44345), FDA published a notice announcing the availability of a draft version of this guidance. FDA received a number of comments when it issued the draft version of this guidance. We have considered the comments on the draft guidance carefully and have made some changes to address those comments. The guidance has been revised to clarify the principles on which our current and developing practices are based. We have also added general internal timelines for important milestones associated with the review process.

The GRMPs also include the agency's current best practices, as well as goals for review management improvements. The GRMPs are an important foundational component of FDA's program to more fully implement a quality systems approach for the new drug and biologics review and approval process.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on GRMPs for PDUFA products. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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 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 document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6404 Filed 3–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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 the use of automated collection techniques or other forms of information technology.

Proposed Project: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915–0036)—Extension

The HEAL program assures the availability of funds for loans to eligible students who desire to borrow money to pay for their educational costs. HEAL Lenders use the Lenders Application for Insurance Claim to request payment from the Federal Government for federally insured loans lost due to borrowers death, disability, bankruptcy, or default. The Request for Collection Assistance form is used by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers.

The burden estimates are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response (minutes)	Total burden hours
Lender's Application for Insurance Claim	20	75	1,500	30	750
Request for Collection Assistance	20	1,260	25,200	10	4,208
Total	20				4,958

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 25, 2005.

Tina Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–6354 Filed 3–30–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

[DHS–2005–0025]

Directorate of Information Analysis and Infrastructure Protection (IAIP); Open Meeting of National Infrastructure Advisory Council (NIAC)

AGENCY: Directorate of Information Analysis and Infrastructure Protection.

ACTION: Notice of meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet on Tuesday, April 12, 2005, from 1:30 p.m. to 4:30 p.m. at the National Press Club in Washington, DC. The meeting will be open to the public. Limited seating will be available. Reservations are not accepted. The NIAC advises the President of the United States on the security of critical infrastructures which include banking and finance, transportation, energy, manufacturing, and emergency government services. At this meeting, the NIAC will be briefed on the status of several Working Group activities in which the Council is currently engaged.

DATES: The NIAC will meet Tuesday, April 12, 2005, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: The NIAC will meet at the National Press Club, 529 14th Street, NW., Washington, DC. You may submit comments, identified by DHS Docket DHS–2005–0025 by one of the following methods:

- *EPA Federal Partner EDOCKET Web site: http://www.epa.gov/feddocket.* Follow the instructions for submitting comments on the Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail/Hand Delivery/Courier:* Department of Homeland Security, Attn: Ms. Nancy J. Wong, Infrastructure Coordination Division, Directorate of Information Analysis and Infrastructure Protection/703–235–5352, Anacostia Naval Annex, 245 Murray Lane, SW., Building 410, Washington, DC 20582, 7:30 a.m. to 4 p.m.

Instructions: All submissions received must include the DFHS–2005–0025. All comments received will be posted without change to *http://www.epa.gov/feddocket*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Nancy J. Wong, NIAC Designated Federal Official, telephone 703–235–5352.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Draft Agenda of Committee Meeting on April 12, 2005:

I. Opening of Meeting
   Nancy J. Wong, U.S. Department of Homeland Security (DHS)/ Designated Federal Official, NIAC
II. Roll Call of Members
   Nancy J. Wong
III. Opening Remarks and Introductions
   NIAC Chairman, Erle A. Nye, Chairman of the Board, TXU Corp.
   NIAC Vice Chairman, John T.