Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis on Monitoring of HCV Infection on Associated Diseases'' will be available at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, on or before January 6, 2000, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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: September 13, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–26303 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0265]

Guidance for Industry on Qualifying for Pediatric Exclusivity; Availability; Revised

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act.'' FDA is publishing this revised guidance to assist industry in interpreting provisions of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This guidance will remain in effect until superseded by regulations or new guidance.

DATES: Comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Manufacturers Assistance and Communications Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, FAX 301–594–6197, e-mail ''crescenzit@cder.fda.gov'', or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852,301–827–0641, FAX 301–827–0644, e-mail ''esber@cber.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a revised guidance for industry entitled ''Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act.'' Section 111 of the Modernization Act (Public Law 105–115), signed into law by President Clinton on November 21, 1997, created section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain an additional 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits information relating to the use of the drug in the pediatric population. FDA plans to issue regulations through notice-and-comment rulemaking to implement the pediatric exclusivity provisions of the Modernization Act. The agency is publishing this procedural guidance to explain how the agency intends to implement section 505A of the act in the interim. The guidance will be updated as appropriate. This guidance will remain in effect until superseded by regulations or new guidance.

This guidance describes FDA's current thinking on how sponsors may qualify for pediatric exclusivity under section 505A of the act. The guidance includes the following topics: (1) Whether studies for certain drugs will be requested under section 505A(a) or (c), (2) the definition of pediatric studies, (3) the content and format of an FDA request for pediatric studies, (4) how an applicant can obtain an FDA written request, (5) the content of a written agreement for the conduct of pediatric studies, (6) the definition of commonly accepted scientific principles, (7) the filing of reports of studies, (8) acceptance of studies by FDA, (9) scope and nature of pediatric exclusivity, (10) publication of exclusivity determinations, (11) treatment of information submitted in support of a request for pediatric exclusivity, (12) how pediatric studies required under FDA regulations may qualify for pediatric exclusivity, and (13) what happens after January 1, 2002, the sunset date for the pediatric exclusivity provisions of the Modernization Act.

This level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the implementation of section 505A of the

act and pediatric exclusivity. 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance 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.

II. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for proposed pediatric studies is already covered by the collection of information on investigational new drug application regulations (21 CFR part 312) submitted to the Office of Management and Budget (OMB) for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection and assigned OMB control number 0910–0014. The approval expires on December 31, 1999.

III. Electronic Access

Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' and at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: September 28, 1999.

Margaret M. Dotzel,

Acting Associate Commssioner for Policy.

[FR Doc. 99–26224 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995.

Proposed Project: Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915–0044)—Revision

The HPSL Program provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, an associate degree, a baccalaureate degree, or a graduate degree in nursing. Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The deferment form (HRSA form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR—HRSA form 501) provides the Federal Government with information from participating and non-participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The estimate of burden is as follows:

Form No.	Number of respondents	Response per response	Total annual respondents	Hours per respondents	Total burden hours
Defer–HRSA–519	10,358	1	10,358	[1] 10	1,726
AOR–HRSA–501	1,302	1	1,302	[2] 4	5,208
Total Burden	11,660		11,660		6,934

[1] Minutes.
[2] Hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 30, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–26225 Filed 10–7–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G–Education,.

Date: November 3–5, 1999.

Agenda: 1 p.m. to 12 p.m.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave, NW., Washington, DC 20007.

Contact Person: Harvey P. Stein, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rm. 611B, Rockville, MD 20892, 301–496–7481.