Science Board BPA Subcommittee. The Science Board will discuss 2009 agenda topics. The Science Board will also hear an overview of current methods for detection of contaminants in FDA-regulated products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 24, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 16, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carlos Peña at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 3, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8–24051 Filed 10–8–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0520]**

### Draft Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products'' dated October 2008. The draft guidance document provides manufacturers of cellular and gene therapy (CGT) products with recommendations for developing tests to measure potency. The recommendations are intended to clarify the potency information needed to support an Investigational New Drug Application (IND) or a Biologics License Application (BLA).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 7, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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:** Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products'' dated October 2008. The draft guidance document provides manufacturers of CGT products with recommendations for developing tests to measure potency. The recommendations are intended to clarify the potency information needed to support an IND or a BLA. Because potency measurements are designed specifically for a particular product, the guidance does not make recommendations regarding specific types of potency assays, nor does it propose criteria for product release.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 statutes and regulations.

#### II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211 has been approved under 0910–0139, expiration date September 20, 2008; the collections of information in 21 CFR part 312 has been approved under 0910–0014, expiration date May 31, 2009; the collections of information in 21 CFR part 601 has been approved under 0910–0338, expiration date June 30, 2010.

#### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation

at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: October 1, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–24052 Filed 10–8–08; 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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), 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, e-mail *paperwork@hrsa.gov* or 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) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915–0047)—Extension**

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, that schools know the history and status of each loan account, that schools pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The annualized estimates of burden are as follows:

RECORDKEEPING REQUIREMENTS

| Regulatory/section requirements | Number of recordkeepers | Hours per year | Total burden hours |
|---|---|---|---|
| HPSL Program: | | | |
| 57.206(b)(2), Documentation of Cost of Attendance | 432 | 1.17 | 505 |
| 57.208(a), Promissory Note | 432 | 1.25 | 540 |
| 57.210(b)(1)(i), Documentation of Entrance Interview | 432 | 1.25 | 540 |
| 57.210(b)(1)(ii), Documentation of Exit Interview | *472 | 0.33 | 156 |
| 57.215(a)&(d), Program Records | *472 | 10 | 4,720 |
| 57.215(b), Student Records | *472 | 10 | 4,720 |
| 57.215(c), Repayment Records | *472 | 18.75 | 8,850 |
| HPSL Subtotal | 472 | | 20,031 |
| NSL Program: | | | |
| 57.306(b)(2)(ii), Documentation of Cost of Attendance | 300 | 0.3 | 90 |
| 57.308(a), Promissory Note | 300 | 0.5 | 150 |
| 57.310(b)(1)(i), Documentation of Entrance Interview | 300 | 0.5 | 150 |
| 57.310(b)(1)(ii), Documentation of Exit Interview | *435 | 0.17 | 74 |
| 57.315(a)(1)&(a)(4), Program Records | *435 | 5 | 2,175 |
| 57.315(a)(2), Student Records | *435 | 1 | 435 |
| 57.315(a)(3), Repayment Records | *435 | 2.51 | 1,092 |
| NSL Subtotal | 435 | | 4,166 |

*Includes active and closing schools.

HPSL data includes active and closing Loans for Disadvantaged Students (LDS) program schools.

REPORTING REQUIREMENTS

| Regulatory/section requirements | Number of respondents | Responses per respondent | Total annual responses | Hours per response | Total hour burden |
|---|---|---|---|---|---|
| HPSL Program: | | | | | |
| 57.206(a)(2), Student Financial Aid Transcript | 4,600 | 1 | 4,670 | .25 | 1,150 |
| 57.208(c), Loan Information Disclosure | 432 | 68.73 | 29,692 | .0833 | 2,473 |
| 57.210(b)(1)(i), Entrance Interview | 432 | 68.73 | 29,692 | 0.167 | 4,959 |
| 57.210(b)(1)(ii), Exit Interview | *472 | 12 | 5,664 | 0.5 | 2,832 |