

estimates the total annual industry burden to collect and provide the previous information to 216,600 burden hours.

Table 1 of this document is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and

distributors) to comply with the voluntary reporting requirements of FDA's recall regulations.

In the **Federal Register** of June 3, 2008 (73 FR 31696), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates on average the burden of collection for recall information to be as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Recall strategy 7.42 | 2,166 | 1 | 2,166 | 20 | 43,320 |
| Firm initiated recall and recall communications 7.46 and 7.49 | 2,166 | 1 | 2,166 | 30 | 64,980 |
| Recall status reports and followup 7.53 | 2,166 | 4 | 8,664 | 10 | 86,640 |
| Termination of a recall 7.55(b) | 2,166 | 1 | 2,166 | 10 | 21,660 |
| Total | | | | | 216,600 |

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

The annual reporting burdens are explained as follows:

Reporting

A. Recall Strategy

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the agency estimates it will receive 2,166 responses annually.

B. Firm Initiated Recall and Recall Communications

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, and biologicals to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the agency estimates it will receive 2,166 responses annually for each.

C. Recall Status Reports

Request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This collection of information will generate approximately 8,664 responses annually.

D. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The agency estimates it will receive 2,166 responses annually.

Dated: October 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally,

the Science Board provides advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on Friday, October 31, 2008, from 8 a.m. to 3:30 p.m.

Location: Hilton, Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, carlos.peña@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will hear about and discuss a review of the draft assessment of Bisphenol A (BPA) for use in food contact applications by the

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.

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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