

TABLE 2.—ESTIMATED RECORDKEEPING BURDEN¹—Continued

	Number of Recordkeepers	Number of Records per Recordkeeping	Total Records	Hours per Record	Total Hours
Total					90

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

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-3980 Filed 2-25-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0391]

Guidance for Industry on Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes; 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 “Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes.” This guidance provides recommendations to applicants on

information to include in support of parametric release for sterile products terminally sterilized by moist heat when submitting a new drug application (NDA), abbreviated new drug application (ANDA), new animal drug application (NADA), abbreviated new animal drug application (ANADA), or biologics license application (BLA).

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; the Communications Staff (HFV-12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855; the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Marla Stevens-Riley, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9310, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210; or

Mai Huynh, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8273.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes.” The guidance addresses the information that should be submitted in an NDA, ANDA, NADA, ANADA, or BLA in support of parametric release for sterile products terminally sterilized by moist heat.

“Parametric release” is defined as a sterility assurance release program where demonstrated control of the sterilization process enables a firm to use defined critical process controls, in lieu of the sterility test, to fulfill the intent of 21 CFR 211.167(a). Under this strategy, market release of terminally sterilized products can be based upon meeting the defined sterilization parameters and not on performing an approved sterility test. Meeting the requirements of the parametric release process can provide greater assurance that a batch meets the sterility requirement than can be achieved with a sterility test of finished units drawn from the batch.

Parametric release allows manufacturers to replace sterility testing of samples drawn from the finished product as a release criterion with acceptance criteria for the control of identified process parameters. Parametric release of the batch is then based on documented evidence of the control of critical parameters, removing the need for testing of samples drawn from the finished product.

An application to FDA is required to obtain approval for parametric release. The approval of parametric release is based on an assessment of the applicant’s proposed critical process parameters and how they are controlled. Demonstrated reliability of the production terminal sterilization cycle, microbiological control and monitoring, and control of production cycle parameters within established validated limits is part of this assessment. FDA conducts scientific evaluation of the parametric release program as part of a cooperative effort between FDA product reviewers and the compliance program.

On August 5, 2008 (73 FR 45454), FDA announced the availability of the draft version of this guidance. The public comment period closed on October 6, 2008. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. Most of the changes to the guidance were made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on inclusion of recommended information to support applications for parametric release of human and veterinary drug products terminally sterilized by moist heat processes. 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information requested in the guidance is covered under FDA regulations at 21 CFR 314.50, 314.70, and 314.81(b)(2) for human drugs; 21 CFR 514.1, 514.8, 514.8(b)(4) and (c) for animal drugs; and 21 CFR 601.2 and 601.12 for biologics. The collection of information is approved under the following OMB control numbers: 0910–0001 for human drugs, 0910–0600 for animal drugs, and 0910–0338 for biologics.

III. Comments

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Dated: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3978 Filed 2–25–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Eye Institute Special Emphasis Panel, NEI K99 Grant Applications.

Date: March 1, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel—Chevy Chase Pavilion Washington, DC 20015.

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Officer, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892, 301–451–2020, kenshalod@nei.nih.gov.

This Notice is late due to administrative procedures.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 17 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–3784 Filed 2–25–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1514–N]

Medicare Program; Public Meetings in Calendar Year 2010 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2010 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. Discussion will be directed toward responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

DATES: *Meeting Dates:* The following are the 2010 HCPCS public meeting dates:

1. Tuesday, May 4, 2010, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.)

(Drugs/Biologics/Radiopharmaceuticals/Radiologic Imaging Agents).

2. Wednesday, May 5, 2010, 9 a.m. to 5 p.m., e.d.t. (Drugs/Biologics/Radiopharmaceuticals/Radiologic Imaging Agents).

3. Tuesday, May 25, 2010, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).

4. Wednesday, May 26, 2010, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).

5. Thursday, May 27, 2010, 9 a.m. to 5 p.m., e.d.t. (Orthotics and Prosthetics).

6. Tuesday, June 8, 2010, 9 a.m. to 5 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories).

Deadlines for Primary Speaker

Registration and Presentation Materials: The deadline for registering to be a primary speaker, and submitting materials and writings that will be used in support of an oral presentation are as follows:

- April 20, 2010 for the May 4 and 5, 2010 public meetings.

- May 11, 2010 for the May 25, 26 and 27, 2010 public meetings.

- May 25, 2010 for the June 8, 2010 public meeting.

Deadline for Attendees that are Foreign Nationals (reside outside the