In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. *E-mail address: OPREinfocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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 through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 29, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8–17721 Filed 8–4–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0391]

Draft Guidance for Industry on Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist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 This draft guidance provides recommendations to applicants on information to include in support of parametric release for sterile products terminally sterilized by moist heat when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: 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 October 6, 2008.

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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800.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

Deborah Trout, Center for Biologics Evaluation and Research (HFM–675), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20892, 301–827–3031; 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 draft 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 draft guidance addresses the information that should be submitted in an approved 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) 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 draft 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

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.

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 and 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 document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17855 Filed 8–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0417]

Draft Guidance for the Public and the Food and Drug Administration Staff on Convening Advisory Committee Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings.'' This draft guidance is intended to provide guidance on when FDA should consider referring a matter to an advisory committee. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of four guidances intended to improve FDA's advisory committee procedures.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (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 October 6, 2008.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 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: Jill Hartzler Warner, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings,'' dated July 2008. Advisory committees provide FDA with independent, expert advice on a range of complex scientific and technical issues related to the products it regulates. These issues typically focus on a specific food or medical product, a class of foods or medical products, the development and implementation of a specific regulatory program, or the development and implementation of a regulatory policy. Advisory committee meetings also facilitate public discussion of important topics and provide a means for the public to provide comments to the agency.

To enhance the transparency of FDA's advisory committee program, the agency is publishing this draft guidance to provide its current thinking on when to bring a matter to an advisory committee. In some instances, FDA refers a matter to an advisory committee because it is required to do so by law. In others, FDA convenes an advisory committee meeting at its own discretion. Regardless, FDA recognizes that advisory committee meetings demand significant resource commitments by advisory committee members, sponsors, and other public participants, as well as for FDA itself, and should be used for important matters. The draft guidance is intended to clarify how the agency identifies which matters should be referred.

In developing this draft guidance, FDA has been mindful of the legal requirements of the Federal Advisory Committee Act (FACA), other relevant statutes, regulations, guidance, and policies, and the goals of FDA's of advisory committee program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance represents the agency's current thinking on when FDA convenes an advisory committee meeting. 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 regarding this document.