

program is a success, there will be a new, proven resource available to health care providers to improve their ability to treat pain and addiction co-occurring in the provider's patients. In order to evaluate the effectiveness of the program, information will be collected from health care providers before exposure to the web based materials (pre-test), after exposure to the web based materials (post-test), and 4–6 weeks after the

program has been completed (follow-up).

Frequency of Response: On occasion.

Affected Public: Volunteer health care providers who treat patients with pain.

Type of Respondents: Physicians, nurse practitioners, and physician assistants.

The annual reporting burden is as follows:

Estimated Number of Respondents: 80.

Estimated Number of Responses per Respondent: 3.

Average Burden Hours per Response: 0.75.

Estimated Total Annual Burden Hours Requested: 180.

The annualized cost to respondents is estimated at: \$11,925. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated annual burden hours requested
Physicians	60	3	0.75	135
Other primary care providers (e.g., nurse practitioners, physician assistants)	20	3	0.75	45

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Scudder Quandra, Project Officer, NIH/NIDA/CCTN, Room 3105, MSC 9557, 6001 Executive Boulevard, Bethesda, MD 20892–9557 or e-mail your request, including your address to scudderq@nida.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 25, 2010.

Mary Affeldt,

Executive Officer (OM Director), NIDA.

[FR Doc. 2010–2694 Filed 2–5–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0410] (formerly Docket No. 2006D–0191)

Guidance for Industry and Food and Drug Administration; Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials.” This guidance summarizes FDA’s current thoughts on the appropriate use of Bayesian statistical methods in the design and analysis of medical device clinical trials.

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

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, Bldg. 66, rm. 4617, 10903 New Hampshire Ave., Silver Spring, MD 20993 or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in

processing your request, or fax to CDRH at 301–847–8149. The 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 information on electronic access to the guidance.

Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document. Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Greg Campbell, Center for Devices and Radiological Health, Bldg. 66, rm. 2110, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5750; 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.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance outlines FDA’s current thinking on the use of Bayesian statistical methods in medical device clinical trials. Bayesian statistical methods are currently used in a variety of medical device applications to FDA. This guidance includes a general description of Bayesian methods, discussions on design and analysis of Bayesian medical device clinical trials, the benefits and difficulties with the Bayesian approach, and comparisons with standard (frequentist) statistical methods. Additionally, some ideas on

using Bayesian methods in post-market studies are presented.

The draft version of this document was issued on May 23, 2006, for comment. A public meeting to discuss the document was held on July 27, 2006. FDA received several hundred specific comments on the guidance. There were many comments of a specific technical nature; for example, a set of comments regarding our discussion of prior distributions, the meaning of “non-informative” priors, and how we might evaluate the choice of a prior led us to make some changes and additions to the document. As another example, the central importance of the concept of “exchangeability” was revealed in some of the comments and has recently become more apparent; thus the discussion of exchangeability has been greatly expanded. Many comments of a more regulatory nature (e.g. specific issues regarding implementation of Bayesian methods in a regulatory setting) were also addressed in the revision. To the extent possible, editorial comments regarding the presentation of the statistical or technical issues and/or the writing were addressed.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on “Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials.” 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive “Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials,” you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1601 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/>

GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

IV. Paperwork Reduction Act of 1995

This 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 807 have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), electronic or written 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.

Dated: January 15, 2010.

Jeffrey Shuren,

Director, Center for Devices and Radiological Health.

[FR Doc. 2010-2596 Filed 2-5-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0592]

Guidance for Industry on the Contents of a Complete Submission for the Evaluation of Proprietary Names; 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 “Contents of a Complete Submission for the Evaluation of Proprietary Names” (proprietary names submission guidance). This guidance

provides recommendations to industry regarding the submission of a complete package that FDA intends to use to assess the safety of proposed proprietary names for drugs, including biological products, and other factors that, in association with the name, can contribute to medication errors. In addition, FDA intends to use this information in the assessment of promotional aspects of proposed proprietary names.

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; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The 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 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:

Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993-0002, 301-796-2360; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Contents of a Complete Submission for the Evaluation of Proprietary Names.” In performance goals under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV), FDA agreed to implement various measures to reduce medication errors