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]

BILLING CODE 4160–01–S

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

related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed to publish guidance on the contents of a complete submission package for a proposed proprietary name for a drug/biological product. FDA also agreed to performance goals for review of proprietary names submitted during the investigational new drug application (IND) phase or with a new drug application (NDA) or biologics license application (BLA); the goals stipulate that a complete submission is required to begin the review clock. (See section IX.A of the goals letter at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

This proprietary names submission guidance is intended to promote prevention of medication errors by assisting industry in the submission of complete product information that will help FDA to evaluate the safety of proposed proprietary drug and biological product names, taking into account 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.

This proprietary names submission guidance applies to prescription drug products, including biologics, that are the subject of an IND, NDA, abbreviated new drug application (ANDA), or BLA; and nonprescription drug products that are the subject of an IND, NDA, or ANDA.

The proprietary names submission guidance does not address other performance goals under PDUFA IV, including developing FDA internal policies and procedures to ensure that proprietary name review goals are met; developing guidance on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors; developing guidance on proprietary name evaluation best practices; and developing and implementing a pilot program for evaluating proposed proprietary names. These performance goals are or will be addressed elsewhere.

In the **Federal Register** of November 24, 2008 (73 FR 71009), FDA announced the availability of a draft guidance for industry entitled "Contents of a Complete Submission for the Evaluation of Proprietary Names" and invited comments. Many comments discussed topics that were beyond the scope of the proprietary names submission guidance, including other performance goals under PDUFA IV that are addressed in other public dockets. These comments concerned the contents of any industry-sponsored reviews and data for submission to FDA under the pilot program described in the FDA concept paper entitled "PDUFA Pilot Project Proprietary Name Review" (concept paper) (73 FR 58604, October 7, 2008). FDA acknowledges that information in the proprietary names submission guidance could be useful to participants in the voluntary pilot program for proprietary name review. However, the proprietary names submission guidance does not describe the information needed by FDA to evaluate proposed proprietary names under the pilot program. Rather, the purpose is limited to informing industry about what information is needed by FDA to evaluate proposed proprietary names within PDUFA IV goal dates under the traditional review process. We welcome submission of comments about the tools and methods FDA uses for its analysis of proposed proprietary names under the pilot program to docket number FDA–2008–N–0281.

After considering comments on the draft guidance, FDA has issued the proprietary names submission guidance. Changes made to the guidance were editorial and primarily clarifying in response to comments. The revisions included: (1) Clarifying that the purpose of this guidance is to provide industry with a complete listing of the information FDA needs to evaluate a proposed proprietary name under the traditional review process; (2) adding the respective PDUFA IV review performance timeframes for complete submissions of a proposed proprietary name submitted during the IND phase or with an NDA, BLA, or supplement; and (3) referencing the concept paper[1] for a complete discussion of the tools and methods used for FDA's safety evaluation that are mentioned in the proprietary names submission 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 the contents of a complete submission for the evaluation of proprietary names. 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.

[1] Available on the Internet at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf.*

II. 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.

III. Paperwork Reduction Act of 1995

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IV. Electronic Access

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

Dated: February 3, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–2660 Filed 2–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Purified Inactivated Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3′-UTR of Dengue Types 1,2,3, and 4

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.