ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. Burden per response (in hrs.)
Public Health Laboratorians	Special Data Call	200	4	30/60

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–01409 Filed 1–23–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0056]

Biofilms, Medical Devices, and Anti-Biofilm Technology—Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Biofilms, Medical Devices, and Anti-Biofilm Technology—Challenges and Opportunities.'' FDA is cosponsoring this workshop with the Center for Biofilm Engineering of Montana State University. The purpose of the public workshop is to initiate dialogue between academia, industry, and U.S. Government scientists on the science of developing products to address biofilm formation. Topics of discussion include current scientific and medical research on biofilms, their impact on medical devices, and biofilm prevention strategies and their public health impact.

DATES: The public workshop will be held on February 20, 2014, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Geetha Jayan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3622, Silver Spring, MD 20903–0002, 301–796–6300, email: *geetha.jayan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. February 7, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, (email: *susan.monahan@fda.hhs.gov* or phone: 301–796–5661) no later than February 7, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. (EST) on February 6, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after February 14, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on biofilms and anti-biofilm technology on medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is March 20, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available

approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

I. Background

Biofilms play a key role in the development of device-related and other healthcare associated infections. Published literature indicates that biofilms are a major culprit in the development of resistant infections. However, the biochemical and physiochemical characteristics of biofilms are not widely understood.

With the increasing use of implanted and indwelling devices, understanding biofilm development on these devices and factors that impact biofilm formation is critical. Research on the basic science of biofilms may provide insight on device-associated biofilms, ultimately advancing research on technologies that are intended to prevent biofilm formation.

This public workshop seeks to share scientific information between academia, industries interested in developing products to address biofilm contamination, and U.S. Government scientists.

II. Topics for Discussion at the Public Workshop

FDA seeks to address and receive comments on the following topics:

1. Research on biofilms and their public health impact.

2. Challenges faced by the scientific community, government, and industry on addressing biofilm contamination of medical devices.

3. Critical areas of research that will address the scientific and clinical challenges faced by the stakeholders when developing technologies that are intended to prevent biofilm formation.

This public workshop may also form the basis for future discussions related to novel biofilm prevention technologies that could benefit U.S. public health.

Dated: January 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01412 Filed 1–23–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0284]

Pediatric Studies of Sodium Nitroprusside Conducted in Accordance With the Public Health Service Act; Availability of Summary Report and Requested Labeling Changes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a summary report of the pediatric studies of sodium nitroprusside conducted in accordance with the Public Health Service Act (the PHS Act) and is making available requested labeling changes for sodium nitroprusside. The Agency is making this information available consistent with the PHS Act.

FOR FURTHER INFORMATION CONTACT: Lori Gorski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6415, Silver Spring, MD 20993–0002, 301–796–2200, Fax: 301–796–9855, email: *lori.gorski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Sodium Nitroprusside Summary Review

In the **Federal Register** of January 21, 2003 (68 FR 2789), sodium nitroprusside (SNP) was identified as a drug that needed further study in pediatrics. The approved labeling lacked adequate information on dosing, pharmacokinetics, tolerability, and safety information in pediatric patients from birth to 18 years of age who receive SNP for controlled reduction of blood pressure.

A written request (WR) for pediatric studies of sodium nitroprusside was issued on July 8, 2002, to Abbott Laboratories, the holder of the new drug application for sodium nitroprusside. FDA did not receive a response to the written request. Accordingly, the National Institutes of Health (NIH) issued a request for proposals to conduct the pediatric studies described in the written request in July 2004 and awarded funds to Duke University and Stanford University in September 2004 to complete the studies described in the written request.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) submitted clinical study reports for SNP. The two studies are:

- NICHD–2003–09–DR–SNP1: A randomized double-blind, parallel group, dose-ranging, effect-controlled, multicenter study of intravenous infusions of SNP in pediatric patients who require deliberate, controlled relative-induced hypotension for at least 2 hours.
- NICHD–2003–09–LT–SNP2: A multicenter, randomized, double-blind, placebo-controlled, parallel group study to determine the pharmacodynamics of sodium nitroprusside during the prolonged infusion in pediatric subjects. This study was a withdrawal to placebo study.

Upon completion of these pediatric studies, a report of the pediatric studies of sodium nitroprusside was submitted to NIH and FDA. In the **Federal Register** of October 3, 2012 (77 FR 60441), FDA announced the opening on August 31, 2012, of docket FDA–2012–N–0284 for submission of data from pediatric studies of sodium nitroprusside. The data submitted to the docket were submitted in accordance with section 409I of the PHS Act (42 U.S.C. 284m) and were the same data submitted to investigational new drug application 71,979, with the exception that personal privacy information had been redacted from the data submitted to the docket.

The sodium nitroprusside docket remained opened for public comment from October 3, 2012, through November 2, 2012. There were no comments submitted to the docket during that time, and a memorandum for the record stating such was posted to the docket on November 5, 2012.

During the review of the submission, the Division of Cardiovascular and Renal Products identified inconsistencies in subject numbers between the pharmacokinetic/pharmacodynamic (PK/PD) analysis set and the ITT–E (intent to treat-efficacy) population in the study report NICHD–2003–09–DR–SNP1 and notified NIH. In a meeting with FDA on November 29, 2012, NIH indicated that that they identified treatment assignment inconsistencies between the two datasets and provided a strategy for addressing the concern and performing reanalysis. The need for reanalysis resulted in suspension of the review as of November 29, 2012. The corrected datasets and reanalysis were provided to the Agency and submitted to the docket on September 26, 2013.

The key findings of this submission are:

- The blood pressure lowering effect of SNP was demonstrated in both of the trials.