DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0616]

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.'' This guidance identifies cybersecurity issues that manufacturers should consider in preparing premarket submissions for medical devices in order to maintain information confidentiality, integrity, and availability. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 12, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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

FOR FURTHER INFORMATION CONTACT: Abiy Desta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1682, Silver Spring, MD 20993–0002, 301–796–0293, *Abiy.Desta@fda.hhs.gov;* 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 draft guidance provides recommendations to consider and document in FDA medical device premarket submissions to provide effective cybersecurity management and to reduce the risk that device functionality is intentionally or unintentionally compromised. The need for effective cybersecurity to assure medical device functionality has become more important with the increasing use of wireless, Internet- and network-connected devices and the frequent electronic exchange of medical device-related health information.

II. Significance of Guidance

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 management of cybersecurity in medical devices. 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 draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health 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 from the Center for Biologics Evaluation and Research at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,'' you may either send an email 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 1825 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. 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.*

Dated: June 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14167 Filed 6–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0616]

Guidance for Industry on Codevelopment of Two or More New Investigational Drugs for Use in Combination; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The FDA is announcing the availability of a guidance for industry entitled ''Codevelopment of Two or More New Investigational Drugs for Use

in Combination.'' This guidance is intended to assist sponsors in the codevelopment of two or more investigational drugs that have not been previously developed for any indication (*i.e.,* ''new investigational drugs'') to be used in combination to treat a disease or condition. The guidance provides recommendations and advice on how to address certain scientific and regulatory issues that may arise during codevelopment of two or more new investigational drugs. It is not intended to apply to development of combinations of already approved drugs or to development of a single new investigational drug to be used in combination with an already approved drug or drugs. The guidance is not intended to apply to biological products regulated by the Center for Biologics Evaluation and Research or medical devices.

DATES: Submit either electronic or written comments on Agency guidance 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colleen Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 4216, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1114.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of a guidance for industry entitled ''Codevelopment of Two or More New Investigational Drugs for Use in Combination.'' The guidance is intended to assist sponsors in the codevelopment [1] of two or more investigational drugs that have not been previously developed for any indication (*i.e.,* ''new investigational drugs'') to be used in combination to treat a disease or condition. Recent scientific advances have increased our understanding of the pathophysiological processes that underlie many complex diseases, such as cancer, cardiovascular disease, and infectious diseases. This increased understanding has provided further impetus to develop therapeutic approaches that rely primarily or exclusively on combinations of drugs directed at multiple therapeutic targets to improve treatment response and minimize development of resistance. In settings in which combination therapy provides significant therapeutic advantages, there is growing interest in the development of combinations of investigational drugs not previously developed for any indication.

Because existing developmental and regulatory pathways focus primarily on assessment of the safety and effectiveness of a single new investigational drug acting alone, or in combination with an already approved drug, FDA believes guidance is needed to assist sponsors in the codevelopment of two or more new investigational drugs. This guidance is intended to describe a high-level, generally applicable approach. It describes the criteria for determining when codevelopment may be an appropriate option, makes recommendations about nonclinical and clinical development strategies, and addresses certain regulatory process issues. The guidance is not intended to apply to biological products regulated by the Center for Biologics Evaluation and Research or medical devices.

In the **Federal Register** of December 15, 2010 (75 FR 78259), FDA announced the availability of a draft of this guidance. FDA received a number of comments, including multiple comments seeking clarification of the scope and applicability of the guidance, the criteria for determining when codevelopment is appropriate, the evidentiary expectations for the individual new investigational drugs and their use in combination, and the types of regulatory submissions needed for codeveloped products. FDA has carefully considered these comments. The final guidance clarifies the criteria for determining when codevelopment is appropriate and elaborates on strategies for clinical development of the individual new investigational drugs and their use in combination. It also provides a detailed discussion of considerations for submitting Investigational New Drug Applications (INDs) and New Drug Applications (NDAs) . The final guidance clarifies the scope of the drugs to which it applies; it uses the term ''new investigational drug'' to refer to drugs that have not previously been developed for any indication. We have also revised the title of the guidance to reflect this term.

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 development of two or more new investigational drugs for use in combination. 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 either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. 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.*

III. The 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 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 310.305 and 314.80 have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 208.20, 208.24, and 314.70(b) have been approved under OMB control number 0910–0393.

[1] The term *codevelopment* as used in the guidance refers to the concurrent development of two or more new investigational drugs that are intended to be used in combination to treat a disease or condition. A sponsor may elect to codevelop two or more new investigational drugs intended to be marketed as individual agents or to be used in combination as a fixed-combination or copackaged drug.

IV. Electronic Access

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

Dated: June 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14168 Filed 6–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Palliative Care: Conversations Matter Evaluation

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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.

To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact Ms. Adrienne Burroughs, Health Communications Specialist, Office of Communications and Public Liaison, NINR, NIH, Building 31, Room 5B10, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 496–0256, or Email your request, including your address to: *adrienne.burroughs@nih.gov.*

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

Proposed Collection

Palliative Care: Conversations Matter Evaluation –0925—New—National Institute of Nursing Research (NINR), National Institutes of Health (NIH)

Need and Use of Information Collection: NINR developed *Palliative Care: Conversations Matter,* a pediatric palliative care campaign to address the communications challenges faced by health care providers who recommend and provide palliative care to pediatric populations. NINR is launching this effort to increase the use of palliative care for children living with serious illness or life-limiting conditions. The *Palliative Care: Conversations Matter* evaluation will assess the information and materials being disseminated as part of the official campaign. Survey findings will help (1) Determine if the campaign is effective, relevant, and useful to health care providers who recommend and provide palliative care to pediatric populations; (2) to better understand the information needs of health care providers to inform future campaign efforts; and (3) examine how effective the campaign materials are in starting and continuing a pediatric palliative care conversation and addressing the communications needs of health care providers around this topic.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 200.

Estimated Annualized Burden Hours

TABLE A–12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hours)	Total burden hours
Physicians	150	2	20/60	100
Nurses	150	2	20/60	100
Total	300			200

Dated: June 5, 2013.

Amanda Greene,

Science Evaluation Officer, NINR, National Institutes of Health.

[FR Doc. 2013–14173 Filed 6–13–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

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 meetings.

The meetings 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 Institute of General Medical Sciences Special Emphasis Panel; R–13 Conference Grants.

Date: July 9, 2013.

Time: 12:00 p.m. to 5:00 p.m.