Page 8 – Dr. Sven Cramer, altona Diagnostics GmbH

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: February 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02467 Filed 2–6–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0354]

Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws,'' dated August 2010. We are taking this action because the policies stated in the guidance have been superseded by our issuance of final rules on menu and vending machine labeling.

DATES: February 9, 2015.

FOR FURTHER INFORMATION CONTACT: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 25, 2010 (75 FR 52427), we announced the availability of a guidance entitled ''Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws.'' The guidance stated that we were issuing the guidance to: (1) Ensure that industry and State and local governments understand the immediate effects of the law, and (2) clarify the effect of section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and local menu and vending machine labeling laws.

We are withdrawing this guidance because we recently issued two final rules entitled ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments'' and ''Food Labeling; Calorie Labeling of Articles of Food in Vending Machines'' (see 79 FR 71156 (December 1, 2014) and 79 FR 71259 (December 1, 2014), respectively). The preambles for these final rules discuss issues relating to Federalism and to federal preemption of State and local laws and reflect our latest thinking on those issues. Consequently, the guidance no longer reflects our current thinking insofar as the law's effect on State and local menu and vending machine labeling laws is concerned.

Dated: February 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02526 Filed 2–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0798]

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices; Mobile Medical Applications: Guidances 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 two guidance documents. FDA is issuing ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with regulatory requirements for Medical Device Data Systems (MDDS) and two similar radiology device types due to the low risk they pose to patients and the importance they play in advancing digital health. FDA is also issuing an updated version of the guidance document ''Mobile Medical Applications,'' originally issued on September 25, 2013, that has been edited to be consistent with the MDDS guidance document.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for

download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' or the updated version of ''Mobile Medical Applications'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidances to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidances 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 on ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' with the docket number found in brackets in the heading of this document. Identify comments on ''Mobile Medical Applications'' with the docket number FDA–2011–D–0530.

FOR FURTHER INFORMATION CONTACT: *For devices regulated by CDRH:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–5528. *For devices regulated by CBER:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that the progression to digital health offers potential for better, more efficient patient care and improved health outcomes. To achieve this goal requires that many medical devices be interoperable with various types of health information technology, including other types of medical devices. The foundation for such intercommunication is hardware and software that functions to transfer, store, convert formats, or display medical device data without modifying the data or controlling the functions or parameters of any connected medical device.[1] In the **Federal Register** of February 15, 2011 (76 FR 8637), FDA issued a final rule defining MDDS devices, medical image storage devices, and medical image communications devices, reclassifying them from class III (high risk) to class I (low risk). Class I devices are subject to general controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since issuance of the February 2011 final rule, FDA has gained additional experience with these types of technologies and has determined that these devices pose a low risk to the public. Therefore, in the documents that are the subject of this notice, FDA provides guidance on the compliance policy for MDDS devices, medical image storage devices, and medical image communication devices and makes conforming changes to the guidance document ''Mobile Medical Applications.'' FDA issued a notice of availability of the draft guidances on June 25, 2014 (79 FR 36072).

The guidance document, ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices,'' states that FDA does not intend to enforce compliance with the regulatory requirements that apply to MDDS devices, medical image storage devices, and medical image communications devices. Blood Establishment Computer Software (BECS) and accessories to BECS are not MDDS devices. Therefore, this guidance does not address the regulation of those devices, which FDA intends to address in another forum. If you have questions about BECS or BECS accessories, please contact the Office of Communication Outreach and Development, CBER at 800–835–4709, 240–402–7800, or email *ocod@fda.hhs.gov.*

The September 25, 2013, version of the guidance entitled ''Mobile Medical Applications'' has been updated to be consistent with the policy stated in the guidance document ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices.'' The updated version of ''Mobile Medical Applications'' also incorporates additional examples from FDA's mobile medical applications' Web site (see *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm*).

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 medical device data systems, medical image storage devices, and medical image communications devices as well as mobile medical applications. 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 guidances may do so by downloading an electronic copy from the Internet. 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 from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' or ''Mobile Medical Applications'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400001 to identify the guidance ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' or document number 1741 to identify the guidance ''Mobile Medical Applications.''

IV. Paperwork Reduction Act of 1995

The guidance documents ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices'' and ''Mobile Medical Applications'' refer to previously approved information collections found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Review Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 and 809 are approved under OMB control

[1] MDDS are not intended to be used for active patient monitoring.

number 0910–0485; the collections of information in 21 CFR part 803 are approved under OMB control numbers 0910–0437 and 0910–0291; the collections of information in 21 CFR part 806 are approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807 subparts B and C are approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807 subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 subparts A through E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; and the collections of information regarding section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) are approved under OMB control number 0910–0705.

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: February 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02573 Filed 2–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0500 (Formerly Docket No. 2004D–0042)]

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.'' This revised draft guidance, when finalized, will assist manufacturers, packers, and distributors (firms) of human prescription drugs and biologics with meeting the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for prescription drugs when print materials are directed toward consumers. FDA is also announcing the withdrawal of the draft guidance for industry entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.''

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 comments on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by May 11, 2015. Submit either electronic or written comments on the proposed collection of information by April 10, 2015.

ADDRESSES: Submit written requests for single copies of the revised 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 revised draft guidance document.

Submit electronic comments on the revised 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: *Regarding human prescription drugs:* Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–1200. *Regarding human prescription biological products:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.'' This revised draft guidance updates prior FDA policy and describes the Agency's current thinking regarding the brief summary requirement for consumer-directed print prescription drug advertisements. Specifically, the revised draft guidance includes recommendations for developing a consumer brief summary and notes that, so long as firms include appropriate information in a print advertisement as outlined in the revised draft guidance, FDA does not intend to object for a failure to include certain other information.

Additionally, this revised draft guidance provides new recommendations regarding the adequate directions for use requirement for consumer-directed print promotional labeling for prescription drug products. Although the requirement in 21 CFR 201.100(d) for firms to provide adequate information for use is generally fulfilled by providing the full FDA-approved package insert (PI), this revised draft guidance provides that, in exercising its enforcement discretion, FDA does not intend to object for failure to include the full PI with consumer-directed print promotional labeling pieces if firms include the appropriate information as outlined in the revised draft guidance, *i.e.,* the same information in the consumer brief summary. This recommendation is designed to standardize the information consumers receive in print prescription drug product advertisements and promotional labeling and to make information more understandable to consumers.

FDA issued a draft guidance in the **Federal Register** of February 10, 2004 (69 FR 6308), entitled ''Brief Summary: