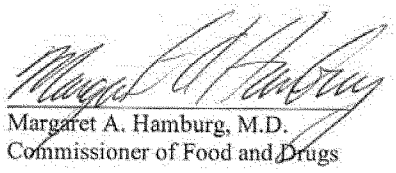
Page 8 – Dr. Sven Cramer, altona Diagnostics GmbH

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 We are taking this action because the policies stated in the guidance have been superseded by our issuance of final rules on menu and vending machine labeling.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