Page 8 – Dr. Cramer, altona Diagnostics GmbH

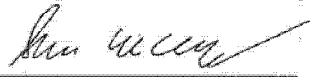
- This test has been authorized only for the detection of MERS-CoV; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. may represent or suggest that this test is safe or effective for the diagnosis of MERS-CoV.

The emergency use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. as described in this letter of authorization, must comply with the conditions and all other terms of this authorization.

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 MERS-CoV is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.



Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21585 Filed 8–31–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1492]

Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Guidance for Industry; 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 (GFI) #227 entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections.'' The guidance provides recommendations to sponsors submitting chemistry, manufacturing, and controls (CMC) data submissions to the Center of Veterinary Medicine (CVM) to support approval of a new animal drug or abbreviated new animal drug.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* 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.

FOR FURTHER INFORMATION CONTACT: Heather Longstaff, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0651, *heather.longstaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2014 (79 FR 62635) FDA published the notice of availability for a draft guidance for industry #227 entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections'' giving interested persons until December 19, 2014, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated October 2014.

GFI #227 provides recommendations to sponsors submitting CMC data submissions to CVM to support approval of a new animal drug or abbreviated new animal drug. The two-phased process allows for two separate CMC submissions, each with its own review clock, and each including complete appropriate CMC information that is available for review at the time of submission. The guidance specifies the technical details of how the process works, the review clocks, the information that is appropriate for each technical section submission, and the possible review outcomes. The guidance also includes CVM's recommendations for meetings between the Division of Manufacturing Technologies and the sponsor during this process to ensure concurrence with the approach used for the CMC technical section.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). This guidance represents the current thinking of FDA on two-phased CMC technical sections. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. 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 514 and section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control numbers 0910–0032 and 0910–0669, respectively.

IV. 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.*

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21583 Filed 8–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 1, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: State and Territorial Health Disparities Survey Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS) is requesting approval from the Office of Management and Budget (OMB) for a new data collection activity for the State and Territorial Health Disparities Survey (STHD Survey).

OMH has a long history of collaborating with states to improve minority health outcomes and reduce health and health care disparities. A strong partnership with state and territorial offices is a key to continue progress toward eliminating health disparities. To best facilitate continued partnerships, OMH needs information about the current activities, challenges, and resources within state and territorial offices of minority health. The State and Territorial Health Disparities Survey is intended to support OMH informational needs by collecting, organizing, and presenting a variety of information about states and U.S. territories, including the current status of minority health and health disparities, the organization and operation of state and territorial offices of minority health, and state/territorial implementation of federal standards and evidence-based practices designed to address disparities and improve minority health. The STHD Survey, which will focus on the activities, staffing, and funding of State Minority Health Entities, is part of a larger project to catalog the extent of health disparities and the activities underway to reduce them in each state and U.S. territory. The STHD Survey supports OMH's goals of working with states and territories to improve the health of racial and ethnic minority populations and eliminate health disparities. While existing, state/territorial-specific information sources (*e.g.,* quantitative data points available from the Agency for Healthcare Research and Quality's *National Healthcare Disparities Report State Snapshots*) offer important facts about the status of health disparities, they do not provide context around the efforts underway to reduce them.

Likely Respondents- Data will be collected using semi-structured telephone interviews with state/territorial minority health entity directors (or their designees) in approximately 54 states and territories (50 states plus the District of Columbia and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands). The purpose of this interview is to collect qualitative information about state/territory program goals and activities, partnerships, and organizational structure, as well as quantitative data elements on staffing and funding.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondents	Average hours per response	Total burden hours
State and Territorial Survey	54	1	1.5	81
Total				81