Page 9 – Dr. Hussong, ARUP Laboratories

- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; 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* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection 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 Zika Virus Detection by RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Zika Virus Detection by RT-PCR test 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* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26532 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by January 3, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0719 for ''Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products (OMB Control Number 0910–0675)—Extension

The guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency, (2) prioritizing the manufacturer's drug products based on medical necessity, (3) identifying actions that should be taken prior to an anticipated period of high absenteeism, (4) identifying criteria for activating the Plan, (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs, (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes, and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer. Based on FDA's data on the number of manufacturers that would be covered by the guidance, we estimate that approximately 70 manufacturers will develop a Plan as recommended by the guidance (*i.e.,* one Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours per year to develop, maintain, and update.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying the FDA Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

The guidance also refers to previously approved collections of information found in FDA regulations. Under the guidance, if a manufacturer obtains information after releasing an MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately at

drugshortages@fda.hhs.gov in adherence to existing recall reporting regulations (21 CFR 7.40) (OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (*see, e.g.,* § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Absenteeism guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA of Plan Activation and Deactivation	2	1	2	16	32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Absenteeism guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop Initial Plan	70	1	70	500	35,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26527 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Zebrafish Embryo Chemical Screening

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests data and information on zebrafish embryo screening tests and protocol design, including pharmacokinetics measurements. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce developmental effects in offspring.

DATES: Receipt of information: Deadline is December 30, 2016.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, supports efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants that replace, reduce, or refine animal use. Multiple regulatory agencies require testing a substance's potential to cause developmental toxicity, which may necessitate the use of large numbers of animals.

Request for Information: NICEATM requests data and information related to chemical screening in the zebrafish embryo. Respondents should provide information on any activities relevant to the development or validation of zebrafish embryo screening assays. NICEATM is particularly interested in how the study design may influence measures of toxicity/bioactivity and the kinetics associated with chemical uptake. For comparative purposes, NICEATM also requests any available data from *in vivo* developmental studies using the same chemicals.

NICEATM specifically requests information on efforts to optimize zebrafish embryo screening tests and protocol design including comparison of (1) zebrafish strains, (2) embryos with and without an intact chorion, and (3) static and static renewal exposures. NICEATM also requests available data on chemical uptake for developing a better understanding of pharmacokinetics in the zebrafish embryo model.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is December 30, 2016. Please contact NICEATM at *niceatm@niehs.nih.gov* if you have questions or concerns about your submission. Responses to this notice will be posted at: *http://ntp.niehs.nih.gov/go/dev-nonanimal.* Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information