Page 7 –Dr. Frieden, Centers for Disease Control and Prevention

- This test has been authorized by FDA under an EUA for use by qualified laboratories designated by CDC;
- This test has been authorized only for the detection of EV-D68; 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 EV-D68 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 EV-D68 2014 rRT-PCR may represent or suggest that this test is safe or effective for the diagnosis of EV-D68.

The emergency use of the authorized EV-D68 2014 rRT-PCR 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 EV-D68 is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

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

Enclosure

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16125 Filed 6–30–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0967]

Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices From Premarket Notification Requirements; 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 guidance entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements.'' This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices from premarket notification requirements. FDA believes the devices identified in this guidance document are sufficiently well understood and do not require premarket notification to assure their safety and effectiveness.

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 ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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: Angela C. Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380.

SUPPLEMENTARY INFORMATION:

I. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA committed to identifying low-risk medical devices to exempt from premarket notification requirements. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices (that no longer meet the ''reserved'' criteria in section 510(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(l))) from premarket notification requirements. FDA believes the devices identified in this guidance document are sufficiently well understood and do not require 510(k) notification to assure their safety and effectiveness.

The draft of this guidance was made available in the **Federal Register** on August 1, 2014 (79 FR 44804). The comment period closed on September 30, 2014. FDA received one comment on the draft guidance requesting that devices classified under 21 CFR 880.6760 (Protective restraint, product code OYS, Patient Bed with Canopy/Restraints) be considered for inclusion in the guidance document. FDA considered the comment and determined it was appropriate to add this device type to the final guidance.

In the process of finalizing the guidance document, the Center for Devices and Radiological Health (CDRH) reviewed additional medical device product codes not included in the draft guidance and determined that there were additional device types which are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness. As a result, the following device types (product codes) were added to the final guidance document: EIB—Syringe, Irrigating (Dental); EWD—Protector, Hearing (Insert); EWE—Protector, Hearing (Circumaural); LEZ—Aids, Speech Training for the Hearing Impaired (AC-Powered and Patient-Contact); LFA—Aids, Speech Training for the Hearing Impaired (Battery-Operated or Non-Patient); KLX—Electroglottograph; LZI—Device, Assistive Listening; LRL—Cushion, Hemorrhoid; KMJ—Lubricant, Patient; OYS—Patient Bed with Canopy/Restraint (see above); HCD—Cannula, Ventricular; GYK—Instrument, Shunt System Implantation; LHM—System, Thermographic, Liquid Crystal; KYA—System, Thermographic, Liquid Crystal, Nonpowered (Adjunctive Use); NUR—Pad, Interlabial; and LZW—Monitor, Spine Curvature.

Additionally, CDRH reviewed the device types (product codes) included in the draft guidance document and determined that two device types (product codes) originally proposed in the draft guidance document should not be included in the final guidance as devices for which FDA intends to exempt from premarket notification requirements: FLL—Thermometer, Electrical, Clinical (21 CFR 880.2910); and GWO—Plate, Cranioplasty, Preformed, Alterable (21 CFR 882.5320). CDRH determined that premarket notification (510(k)) is necessary to assure the safety and effectiveness of these devices. Notably, the FLL product code currently covers thermometers with a range of technologies and intended uses, including those used to screen for potential pandemic contagious diseases. CDRH believes that some thermometer types may be candidates for exemption from premarket notification requirements at a later date, but that thermometers should first be further categorized by technology and/or intended use into distinct product codes. CDRH is actively reviewing this issue and will further consider which of the sub-types may be appropriate to exempt from premarket notification requirements. In addition, CDRH believes that premarket notification (510(k)) is necessary to provide a reasonable assurance of safety and effectiveness for cranioplasty plates (GWO), which are permanent implants and may be constructed of polymeric materials and/or may be resorbable, because FDA must evaluate the material properties and resorption rate in relation to bone healing. CDRH recognizes that manufacturers may not have submitted a 510(k) for these two device types following publication of the draft guidance. As a result, CDRH is providing such manufacturers 90 days following the publication of this notice to submit a 510(k) for these device types; however, distribution and marketing of such devices must cease if a manufacturer receives an order from FDA declaring the device to be not substantially equivalent to any legally marketed predicate device. Finally, CDRH changed the product code listed in the guidance document for Ophthalmic Cameras (21 CFR 886.1120) from HKI—Camera, Ophthalmic, AC-Powered to PJZ—Camera, Ophthalmic, AC-Powered, General Use to clarify the type of AC-powered Ophthalmic Camera CDRH intended to exempt. CDRH also removed LQX—Device, Finger-Sucking (21 CFR 890.3475) from the final guidance because this device type is already classified as class I (general controls) and exempt from premarket notification. Finger-sucking devices (LQX) and cranioplasty plates (GWO) were unintentionally included in the draft guidance.

III. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of the FDA on the Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements. 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.

IV. Electronic Access

Persons interested in obtaining a copy of the guidance 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*. Persons unable to download an electronic copy of ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1300046 to identify the guidance you are requesting.

V. 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 807, subpart E, have been

approved under OMB control number 0910–0120.

VI. 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 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16150 Filed 6–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 31, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions; Section 351(k) Biosimilar Applications OMB Control Number 0910–0719—Extension

The Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which amends the Public Health Service Act (PHS Act) and establishes an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (See sections 7001 through 7003 of the Affordable Care Act.)

Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(k) defines biosimilarity to mean ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.'' (See section 351(i)(2) of the PHS Act.) A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and clinical studies, unless FDA determines, in its discretion, that certain studies are unnecessary in a 351(k) application. (See section 351(k)(2) of the PHS Act.) To demonstrate interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and that the biosimilar biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biosimilar biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. (See section 351(k)(4) of the PHS Act.) Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider. (See section 351(i)(3) of the PHS Act.)

In estimating the information collection burden for 351(k) applications, we reviewed the number of 351(k) applications FDA has received through fiscal year (FY) 2014, as well as the collection of information regarding the general licensing provisions for biologics license applications under section 351(a) of the PHS Act submitted to OMB (approved under OMB control number 0910–0338). For the information collection burden for 351(a) applications, FDA described § 601.2(a) (21 CFR 601.2(a)) as requiring a manufacturer of a biological product to submit an application on forms prescribed for such purpose with accompanying data and information including certain labeling information to FDA for approval to market a product in interstate commerce. FDA also added in the burden estimate the container and package labeling requirements provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimated hours per response for § 601.2, and §§ 610.60 through 610.65, are 860 hours.

In addition, in submitting a 351(a) application, an applicant completes the Form FDA 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use.'' The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. The checklist helps to ensure that the application is complete and contains all the necessary information so that delays due to lack of information may be eliminated. The form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for biological product submissions using FDA Form 356h are included under the applicable requirements approved under OMB control number 0910–0338.

To submit an application seeking licensure of a proposed biosimilar product under section 351(k)(2)(A)(i) and (k)(2)(A)(iii) of the PHS Act, FDA believes that the estimated burden hours would be approximately the same as noted under OMB control number 0910–0338 for a 351(a) application—860 hours. The burden estimates for seeking licensure of a proposed biosimilar product that meets the standards for interchangeability under section 351(k)(2)(B) and (k)(4) would also be 860 hours. Until we gain more experience with biosimilar applications, FDA believes this estimate is