(PMA) for BULKAMID URETHRAL BULKING SYSTEM (PMA P170023) was initially submitted July 31, 2017.

3. *The date the application was approved:* January 28, 2020. FDA has verified the applicant's claim that PMA P170023 was approved on January 28, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19723 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1908]

Policy for Monkeypox Tests To Address the Public Health Emergency; Guidance for Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' On August 4, 2022, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency related to monkeypox. Monkeypox virus is a zoonotic infection (a virus transmitted to humans from animals), caused by *Orthopoxvirus* genus of the *Poxviridae* family similar to variola virus (the causative agent of smallpox), and can spread to humans. Since early May 2022, cases of monkeypox have been reported from countries where the disease is not endemic and continue to be reported in several endemic countries. Rapid detection of monkeypox cases in the United States requires wide availability of diagnostic testing to control the emergence of this contagious infection. This guidance describes FDA's review priorities of emergency use authorization (EUA) requests for monkeypox diagnostic tests, as well as FDA's enforcement policies for various monkeypox tests. The guidance document has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 13, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2022–D–1908 for ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

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 ''Policy for Monkeypox Tests To Address the Public Health Emergency'' to the Office of Policy, 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.

FOR FURTHER INFORMATION CONTACT: Amy Zale, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3423A, Silver Spring, MD 20993–0002, 301–796–0869.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' On August 4, 2022, the Secretary of HHS determined that there is a public health emergency related to monkeypox.[1] On August 9, 2022, the Secretary of HHS determined [2] under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) that there is a public health emergency, or significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad that involves monkeypox virus. On September 7, 2022, the Secretary of HHS determined that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*.[3]

Rapid detection of monkeypox cases in the United States requires wide availability of diagnostic testing to help control the emergence of this contagious infection. This guidance describes FDA's review priorities of EUA requests for monkeypox diagnostic tests, describes FDA's enforcement policies for certain diagnostic tests that are developed by and performed in a laboratory certified under the Clinical Laboratory Improvement Amendments that meets the requirements to perform tests of high complexity, describes FDA's enforcement policies for FDA-cleared or authorized monkeypox diagnostic tests that are modified, describes FDA's enforcement policies for certain serology tests, and provides recommendations for diagnostic test validation.

In light of this public health emergency, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). Although this guidance has been implemented without prior comment, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' 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.

II. 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 Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Policy for Monkeypox Tests To Address the Public Health Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 22003 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

The guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the table below. The guidance also contains a new collection of information not approved under a current collection. These new collections of information were granted a public health emergency (PHE) waiver from the PRA by HHS on August 19, 2022, under section 319(f) of the Public Health Service Act (42 U.S.C. 247d(f)). Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

[1] *See* HHS Secretary Section 319 Declaration (August 4, 2022), available at *https://aspr.hhs.gov/legal/PHE/Pages/monkeypox-4Aug22.aspx.*

[2] *See* HHS Secretary Section 564 Determination (August 9, 2022), available at *https://aspr.hhs.gov/legal/Section564/Pages/Monkeypox-9Aug22.aspx.*

[3] *See* HHS Secretary Section 564 Determination (September 7, 2022), available at *https://aspr.hhs.gov/legal/Section564/Pages/InVitro-Diagnostics-Monkeypox-7Sept22.aspx.*

Guidance title	CFR cite referenced in guidance	Another guidance referenced in guidance	OMB control No(s).	New collection covered by PHE PRA waiver
Policy for Monkeypox Tests to Address the Public Health Emergency.	.....	Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595	
		Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization.	0910–0607	
	803	.....	0910–0437	
	806	.....	0910–0359	
	807, subpart E	.....	0910–0120	
				FDA Notification of Laboratory Development and Validation of Monkeypox Test (including notification template).
				Statements on patient test reports.
				Commercial Manufacturer Test for Monkeypox—EUA Test Summary Information.
				EUA templates for monkeypox tests.

Dated: September 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19709 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2065]

Alternative or Streamlined Mechanisms for Complying With the Current Good Manufacturing Practice Requirements for Combination Products; List Under the 21st Century Cures Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: As required by the 21st Century Cures Act (Cures Act), the Food and Drug Administration (FDA, Agency, or we) is finalizing a list of alternative or streamlined mechanisms for complying with the current good manufacturing practice (CGMP) requirements for combination products. A combination product is a product composed of any combination of a drug, a device, and/or a biological product.

DATES: This notice is published in the **Federal Register** on September 13, 2022.

ADDRESSES: For access to the docket, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130, Silver Spring, MD 20993, 301–796–8930, *john.weiner@fda.hhs.gov* or *combination@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On January 22, 2013, FDA issued a final rule on CGMP requirements for combination products (see 78 FR 4307 and part 4, subpart A (21 CFR part 4, subpart A)) (CGMP Rule). The drugs, devices, and biological products included in combination products are referred to as ''constituent parts'' of the combination product. Combination products include ''single-entity'' combination products, the constituent parts of which are physically, chemically, or otherwise combined or mixed and produced as a single entity (see § 3.2(e)(1) (21 CFR 3.2(e)(1))) (*e.g.,* prefilled syringes and drug-eluting stents), and ''co-packaged'' combination products where the constituent parts are packaged together in a single package or as a unit (see § 3.2(e)(2)) (*e.g.,* a surgical or first-aid kit).[1] Section 4.4 (21 CFR 4.4) outlines how manufacturers of single-entity and co-packaged combination products (hereafter ''CP manufacturers'') can demonstrate compliance with applicable CGMP requirements, including through implementation of a streamlined approach to meet the requirements of both the drug CGMP and the device quality system (QS) regulations.

In December 2016, the Cures Act (Pub. L. 114–255) was signed into law. Section 3038(c) of the Cures Act mandated that FDA publish in the **Federal Register** a list identifying types of combination products and manufacturing processes for which ''good manufacturing processes'' may be adopted that vary from the requirements set forth in § 4.4, or that FDA proposes can satisfy the requirements in § 4.4 through ''alternative or streamlined mechanisms,'' and to review this list periodically. In accordance with this statutory mandate, FDA published a proposed list on June 13, 2018 (83 FR 27609).

FDA received six comments on this proposed list, has considered them, and is now publishing a list after such consideration (see section II of this document). In response to the comments, FDA added and refined examples and provided additional clarity regarding FDA's expectations for CP manufacturers when applying mechanisms presented in this list. FDA also added reference to a guidance on how to request FDA feedback on combination products, which provides additional detail on interacting with

[1] There are also ''cross-labeled'' combination products (§ 3.2(e)(3) and (4)). See Ref. 1 for additional information regarding CGMP requirements for them, as well as use of the ''streamlined approach'' if a device and drug or biological product constituent part of a cross-labeled combination product are manufactured at the same facility.