DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1025]

Emergency Use Authorization of Medical Products and Related Authorities; Draft Guidance for Industry and Public Health Stakeholders; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and public health stakeholders entitled ''Emergency Use Authorization of Medical Products and Related Authorities.'' The purpose of this draft guidance is to explain FDA's current thinking about policies on the authorization of the emergency use of certain medical products under certain sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats. This guidance, when finalized, will replace the current guidance ''Emergency Use Authorization of Medical Products'' (July 2007) and ''Emergency Use Authorization Questions and Answers'' (April 2009).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 3, 2016. Submit either electronic or written comments on the collection of information by June 3, 2016.

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–2016–D–1025 for ''Emergency Use Authorization of Medical Products and Related Authorities; Draft Guidance for Industry and Public Health Stakeholders.'' 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.

Submit written requests for single copies of the draft guidance to Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–8510. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Carol Drew, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4320, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–141526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and public health stakeholders entitled ''Emergency Use Authorization of Medical Products and Related Authorities.'' This draft guidance explains FDA's policies

applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the FD&C Act [1] (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b) as amended or added by PAHPRA (Pub. L. 113–5). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving CBRN agents, including emerging infectious disease threats such as pandemic influenza. PAHPRA clarifies and enhances FDA's authority to support emergency preparedness and response, and fosters the development and availability of medical products for use in these emergencies. These medical products, also referred to as ''medical countermeasures'' (MCMs), include drugs, biological products (*e.g.,* vaccines, blood products, and biological therapeutics), and devices (*e.g.,* in vitro diagnostics and personal protective equipment).

This document is intended to inform industry, government agencies, public health and emergency response stakeholders, and FDA staff of FDA's general recommendations and procedures for:

- Issuance of emergency use authorizations (EUAs) under section 564;
- Implementation of the emergency use authorities set forth in section 564A; and
- Reliance on the governmental pre-positioning authority set forth in section 564B.

Section 564, as amended by PAHPRA, permits the Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Department of Health and Human Services Secretary has made a declaration of an emergency or threat justifying emergency use. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent when available data meet specified criteria to support such uses and there are no adequate, approved, and available alternatives.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs without FDA issuing EUAs, which can be a resource-intensive process. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency and establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;
- Permit FDA to waive otherwise-applicable current good manufacturing practice requirements (*e.g.,* storage or handling) to accommodate emergency response needs;
- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription for each recipient of the MCM or all of the information otherwise required, or by responders who may not otherwise be licensed to dispense if permitted by State law in the State where such dispensing occurs, or if in accordance with an order issued by FDA; and
- Permit the Centers for Disease Control and Prevention to create and issue ''emergency use instructions'' concerning the FDA-approved conditions of use for eligible products.

These authorities, and the definition of eligible products to which they apply, are discussed in the draft guidance.

To enable stakeholders to prepare for potential rapid deployment of MCMs during an actual CBRN emergency, section 564B (also added by PAHPRA) permits Federal, State, and local governments to pre-position (*e.g.,* stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA. This authority is also discussed in the draft guidance.

The provisions of this guidance, when finalized, will replace the current guidance ''Emergency Use Authorization of Medical Products'' (July 2007) and ''Emergency Use Authorization Questions and Answers'' (April 2009).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on emergency use authorization of medical products and related authorities. 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

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA), 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 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.

Reporting and Recordkeeping for Emergency Use Authorization of Medical Products and Related Authorities—OMB Control Number 0910–0595

This guidance explains FDA's policies applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the FD&C Act as amended or added by PAHPRA. FDA has previously submitted, and OMB has approved under OMB control number 0910–0595, reporting and recordkeeping burden estimates for the EUA provisions of this guidance imposed by section 564 of the FD&C Act. This guidance incorporates provisions of the current guidance linked to OMB control number 0910–0595, ''Emergency Use Authorization of Medical Products'' (July 2007).

[1] Section 564 was first added to the FD&C Act by the Project BioShield Act of 2004 (Pub. L. 108–276). Hereafter in this document, statutory references (*e.g.,* ''section __'') are to the FD&C Act, except where otherwise indicated.

Therefore, we are including in this notice the reporting and recordkeeping burden estimates for the EUA provisions included in the prior guidance as imposed by section 564 of the FD&C Act. In addition, sections 564A and 564B of the FD&C Act, as added by PAHPRA, establish streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs without requiring FDA to issue an EUA. These new FDA authorities include provisions that allow FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency. The expiration date extension authority in section 564A applies to any eligible, approved MCM, including eligible MCMs tested through the Federal Shelf-Life Extension Program (SLEP) and State and local public health authorities who maintain their own stockpiles of MCMs.

At this time FDA is not proposing or recommending any changes to the Federal SLEP or procedures for expiration date extensions for products tested by FDA through SLEP. Federal participants in SLEP will continue to submit requests to extend the expiration date of eligible MCMs using established processes.

For drug products not tested within the SLEP program, this guidance recommends that stakeholders consult with the relevant review Center regarding extending the useful shelf-life of a particular product. Stakeholders may need to submit a request for expiry date extensions for stockpiled medical products. Because any such request would be for an approved product, the burden on manufacturers making any such request would be covered by previously approved collections of information, including OMB control number 0910–0139 through May 31, 2018, and OMB control number 0910–0073 through February 28, 2017. FDA anticipates, however, that some requests for expiration date extensions may come from public health authorities maintaining non-Federal stockpiles of MCMs for emergency uses. Therefore, FDA is calculating reporting burden for State and local public health authorities who may need to submit such requests. FDA is not calculating any additional recordkeeping burden for these non-Federal public health authorities because currently these stakeholders maintain records for the MCMs they stockpile, which would include records of any expiration date requests or extensions.

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These collections have been approved as follows: Adverse experience reporting for biological products is approved under OMB control number 0910–0308 through February 28, 2018; adverse drug experience reporting is approved under OMB control number 0910–0230 through December 31, 2018; adverse device experience reporting is approved under OMB control number 0910–0471 through May 31, 2017; investigational new drug application regulations are approved under OMB control number 0910–0014 through February 28, 2019; investigational device exemption reporting is approved under OMB control number 0910–0078 through March 31, 2016; current good manufacturing practices for finished pharmaceuticals are approved under OMB control number 0910–0139 through May 31, 2018; quality system regulations for finished devices are approved under OMB control number 0910–0073 through February 28, 2017; risk evaluation and mitigation strategy requirements are approved under OMB control number 0910–0001 for drug products through December 31, 2017, for biological products under OMB control number 0910–0338 through January 31, 2017, and for devices under OMB control numbers 0910–0078 through March 31, 2016 and 0910–0471 through May 31, 2017.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturer, Request to Issue an EUA or a Substantive Amendment to an Existing EUA	6	3	18	45	810
Manufacturer, Request for FDA Review of a Pre-EUA Package or an Amendment Thereto	13	6	78	34	2,652
Manufacturer of an Unapproved EUA Product; Conditions of Authorization	5	2	10	2	20
Public Health Authority; Unapproved EUA Product; Conditions of Authorization	30	3	90	2	180
Public Health Authority; Request for Expiration Date Extension	7	1	7	2	14
Total					3,676

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers; Unapproved EUA Product	5	2	10	25	250
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					520

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

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/RegulatoryInformation/Guidances/, http://www.regulations.gov,* or *http://www.fda.gov/medicalcountermeasures.*

Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07478 Filed 4–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0643]

Labeling for Biosimilar Products; Draft Guidance for Industry; 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 draft guidance for industry entitled ''Labeling for Biosimilar Products.'' This draft guidance is intended to assist applicants in developing draft prescription drug labeling for proposed biosimilar products. The recommendations for prescription drug labeling in this guidance pertain only to the prescribing information (commonly referred to as the package insert). This draft guidance provides an overview of FDA's recommendations for labeling for biosimilar products licensed under the Public Health Service Act (PHS Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 3, 2016.

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–2016–D–0643 for ''Labeling for Biosimilar Products; Draft Guidance for Industry; Availability.'' 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993, 301–796–1042, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling for Biosimilar Products.'' The Biologics Price Competition and Innovation Act of 2009 (BCPI Act), enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) on March 23, 2010, created an abbreviated