indicating system (FQIS) to prevent development of an ignition source inside the center fuel tank due to electrical fault conditions, using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(h) Alternative Actions for Cargo Airplanes

For airplanes used exclusively for cargo operations: As an alternative to the requirements of paragraph (g) of this AD, do the actions specified in paragraphs (h)(1) and (h)(2) of this AD, using methods approved in accordance with the procedures specified in paragraph (i) of this AD. To exercise this alternative, operators must perform the first inspection required under paragraph (h)(1) of this AD within 6 months after the effective date of this AD. To exercise this alternative for airplanes returned to service after conversion of the airplane from a passenger configuration to an all-cargo configuration more than 6 months after the effective date of this AD, operators must perform the first inspection required under paragraph (h)(1) of this AD prior to further flight after the conversion.

(1) Within 6 months after the effective date of this AD, record the existing fault codes stored in the FQIS processor and then do a BITE check (check of built-in test equipment) of the FQIS. If any nondispatchable fault code is recorded prior to the BITE check or as a result of the BITE check, before further flight, do all applicable repairs and repeat the BITE check until a successful test is performed with no nondispatchable faults found, using a method approved in accordance with the procedures specified in paragraph (i) of this AD. Repeat these actions thereafter at intervals not to exceed 650 flight hours. Modification as specified in paragraph (h)(2) of this AD does not terminate the repetitive BITE check requirement of this paragraph.

(2) Within 60 months after the effective date of this AD, modify the airplane by separating FQIS wiring that runs between the FQIS processor and the center tank wing spar penetrations, including any circuits that might pass through a main fuel tank, from other airplane wiring that is not intrinsically safe, using methods approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Jon Regimbal, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6506; fax: 425–917–6590; email: *Jon.Regimbal@faa.gov.*

Issued in Renton, Washington, on April 15, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–09801 Filed 5–3–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2016–N–1170]

Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is proposing to amend the general biological products standards relating to dating periods and also to remove certain standards relating to standard preparations and limits of potency. FDA is proposing this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities, without diminishing public health protections. This proposed action is part of FDA's retrospective review of its regulations in response to an Executive order.

DATES: Submit either electronic or written comments on this proposed rule or its companion direct final rule by July 18, 2016. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, the Agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will apply any significant adverse comments received on the direct final rule to the proposed rule in developing the final rule. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

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–N–1170 for ''Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological 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: Tami Belouin, 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. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would revise and remove certain general biological products standards, which would update outdated requirements and accommodate new and evolving technology and testing capabilities without diminishing public health protections. FDA is proposing this action because the existing codified requirements are duplicative of requirements that are also specified in biologics license applications (BLAs) or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would remove the requirements contained in § 610.20 (21 CFR 610.20) from the regulations. FDA is proposing this action because the standard preparations listed in the regulation are obsolete, no longer available, or described on a product specific basis in BLAs. In addition, FDA believes that it would no longer be necessary to restrict the source of standard preparations to the Center for Biologics Evaluation and Research (CBER), since appropriate standard preparations can often be obtained from other sources. Furthermore, FDA is proposing to remove § 610.21 because these potency limits are either obsolete or best described on a product specific basis in the BLA. FDA is proposing to revise § 610.50 to remove references to §§ 610.20 and 610.21 and official potency tests and to reflect FDA's updated approach to establishing dates of manufacture. FDA is proposing to amend § 610.53 to remove products no longer manufactured and products for which dating information is identified in the BLA of each individual product, and to reflect updated practices for the remaining products.

C. Legal Authority

FDA is proposing this action under the biological products provisions of the Public Health Service Act (PHS Act), and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

D. Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the rules section of this issue of the **Federal Register**. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received in response to this companion proposed rule will also be considered as comments regarding the direct final rule. FDA is publishing the direct final rule because we believe the rule contains noncontroversial changes and there is little likelihood that there will be significant adverse comments opposing the rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of the direct final rule and that part can be severed from the remainder of the rule (*e.g.,* where, as here, a direct final rule deletes several unrelated regulations), we may adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

If any significant adverse comments to the direct final rule are received during the comment period, FDA will publish, within 30 days after the comment period ends, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be considered comments on the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a document confirming the effective date within 30 days after the comment period ends. Additional information about direct final

rulemaking procedures is set forth in the document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures,'' announced and provided in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance may be accessed at: *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

III. Background

On January 18, 2011, President Barack Obama issued Executive Order 13563, ''Improving Regulation and Regulatory Review'' (76 FR 3821, January 21, 2011). One of the provisions in the Executive Order requires Agencies to consider how best to promote the retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned (76 FR 3821 at 3822). As one step in implementing the Executive Order, FDA published a notice in the **Federal Register** of April 27, 2011 (76 FR 23520), entitled ''Periodic Review of Existing Regulations; Retrospective Review Under E.O. 13563.'' In that notice, FDA announced that it was conducting a review of existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of, and support, advances in innovation that have occurred since those regulations took effect. As part of this initiative, FDA is proposing to update outdated regulations as specified in this proposed rule.

FDA's general biological products standards in part 610 (21 CFR part 610) are intended to help ensure the safety, purity, and potency of biological products administered to humans. The proposed revision and removal of certain general biological products standards are designed to update outdated requirements and accommodate new and evolving manufacturing and control testing technology. The proposed rule provides manufacturers of biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections.

A. Sections 610.20 and 610.21

Standard preparations are generally used to perform lot release testing or other specific product characterization assays. Under the current standard preparations, § 610.20, FDA requires specific standard preparations to be used for a small number of the biological products FDA regulates unless a modification is permitted under § 610.9. Specifically, according to current § 610.20 *Standard preparations,* made available by CBER, are required to be used in the testing of potency or opacity of certain biological products, mostly biological products that were initially licensed several decades ago. Most of these standard preparations requirements are now obsolete, because either CBER no longer provides the listed standard preparations, or the specific biological products are no longer manufactured, or both. In addition, standard preparations to help ensure the safety, purity, and potency of particular biological products can often be obtained from sources other than CBER now, including international sources, or can be developed internally by the applicant. Thus, FDA believes it is no longer necessary to specify CBER as the source of standard preparations in § 610.20. For these reasons, FDA proposes to remove § 610.20. Consistent with current practice and BLAs, CBER will continue to make and supply standard preparations when appropriate, as well as continue to collaborate with external organizations in the development and assessment of physical standard preparations for biological products.

Under the current § 610.21 *Limits of potency,* FDA specifies minimal potency limits to be met for the antibodies and antigens listed. However, most of the biological products subject to the specified potency limits are no longer manufactured. In addition, for those that are still manufactured, or for anyone wanting to manufacture the listed products, FDA's updated practice is to have the potency limit also be specified in the BLA. For this reason, FDA proposes to remove § 610.21. As a result of removing §§ 610.20 and 610.21, we are proposing to remove and reserve part 610, subpart C.

In addition to sometimes being duplicative of information provided in the BLA and unnecessarily restrictive regarding the source of standard preparations, the codification by regulation of many of the standard preparations and limits of potency for certain biological products sometimes does not keep abreast of technological advances in science related to manufacturing and testing. For many years, because of the potential for impeding scientific progress, FDA has not codified additional specific standard preparations and limits of potency for licensed biological products, but instead the standards are established in the BLA. Failure to conform to applicable standards established in the license is grounds for revocation under § 601.5(b)(1)(iv) (21 CFR 601.5(b)(1)(iv)). If the changes proposed in this proposed rule go into effect, FDA will continue to require that each biological product meet standards to assure that the product is safe, pure, and potent, and will continue to require that each lot demonstrate conformance with the standards applicable to that product (see § 610.1) through appropriate testing. Therefore, we expect that standard preparations and potency limits will be established in the BLA and may be changed only in accordance with regulations for reporting post-approval changes (see § 601.12). Furthermore, no lot of any licensed product may be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product (see § 610.1).

FDA is therefore proposing to amend its regulations to remove §§ 610.20 and 610.21 because appropriate standard preparations and potency limits for any listed product are specified during the licensing process on a product specific basis. The removal of §§ 610.20 and 610.21 will also increase regulatory flexibility by allowing industry and FDA to more readily use and incorporate current scientific technology and other appropriate reference materials in the manufacture and regulation of licensed biological products.

B. Sections 610.50 and 610.53

A biological product is expected to remain stable and retain its identity, strength, quality, and purity for a period of time after manufacture when it is properly stored. The dating period limitations regulations provided at §§ 610.50 and 610.53 specify how the date of manufacture for biological products will be determined, when the dating begins, and dating periods for certain biological products. The existing § 610.50 prescribes how the date of manufacture is determined for biological products and relies in part upon §§ 610.20 and 610.21 or official standards of potency (*i.e.,* a specific test method described in regulation). With the proposed removal of §§ 610.20 and 610.21 for reasons described in this document, and as official potency tests no longer exist, FDA is proposing to revise § 610.50 to reflect FDA's updated approach to establishing dates of manufacture.

In addition, current § 610.50(b) does not provide FDA or applicants with flexibility to consider the variety of manufacturing situations and technologies that exist today and which may occur in the future. Since 1977, when the regulation was last amended,

new methods of manufacture and testing often associated with new biological products have been developed. The proposed revision to § 610.50 would allow additional manufacturing activities other than those currently listed to be used to determine the date of manufacture.

The proposed regulatory provision would require the date of manufacture to be identified in the approved BLA. FDA recommends that applicants discuss a suitable date of manufacture with FDA during late clinical development and propose a date of manufacture in the BLA. We consider the underlying science and manufacturing process testing methods in determining the date of manufacture for each specific product. The approved BLA would specify how the date of manufacture would be determined. A proposed paragraph, § 610.50(c), would be added, specifying how the date of manufacture for Whole Blood and blood components would be determined. This provision would assist in complying with the dating periods prescribed for Whole Blood and blood components in the proposed table in redesignated § 610.53(b).

The current table at § 610.53(c) lists dating periods, manufacturer's storage periods, and storage conditions for many biological products. FDA is proposing to revise the current table in § 610.53(c) (which would be redesignated as § 610.53(b)) to remove products where storage conditions and dating periods are established to help ensure the continued safety, potency, and purity of each individual product, based upon information submitted in the relevant BLA. The dating period and storage conditions for these products would be identified in the BLA. FDA is also proposing to revise the current table in § 610.53(c) to delete those products that are no longer manufactured. We are proposing to retain those products, specifically Whole Blood and blood components, whose dating periods are based upon data relating to the anticoagulant or preservative solution in the product, usage, clinical experience, laboratory testing, or further processing. The proposed list has been updated to include currently licensed Whole Blood and blood component products with their applicable storage temperatures and dating periods.

In listing the dating periods for Whole Blood and blood component products, we took into account existing regulations, guidance documents, package inserts for solutions used for manufacture or storage of Whole Blood and blood components, and operator instruction manuals for devices used in the manufacture of Whole Blood and blood component products. Because we understand from these materials that these dating periods are in current use, and because blood establishments can request an exception under § 640.120 (21 CFR 640.120), we do not anticipate significant objections to codifying this information. Similarly, we are proposing to remove § 610.53(d) because it is duplicative of § 640.120. In addition, we recognize that future scientific understanding and new technology, such as the implementation of pathogen reduction technology or the approval of extended storage systems, could affect what dating periods would be necessary, as a scientific matter, for Whole Blood and blood components. For this reason, the proposed rule would allow for changes to the dating periods specified in proposed § 610.53(b) when the dating period is otherwise specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA.

In conclusion, the proposed amendments to the regulations are designed to be consistent with updated practices in the biological product industry and to remove unnecessary or outdated requirements. FDA is proposing this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations to provide flexibility without diminishing public health protection. If finalized, FDA does not anticipate that applicants for licensed biological products would need to revise information in BLAs in order to conform to the proposed revised regulations. Applicants must inform the Agency of any change to an approved application in accordance with § 601.12.

IV. Highlights of the Proposed Rule

FDA is proposing to revise the general biological products standards relating to dating periods and proposing to remove certain standard preparations and limits of potency. These proposed changes are designed to remove unnecessary or outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health protections.

FDA is proposing to remove § 610.20 because the standard preparations listed are obsolete or no longer available; standard preparations to ensure the safety, purity, and potency of a product can best be determined on a product specific basis; and standard preparations may be obtained from other sources. Applicants for biological product licenses currently identify standard preparations for the product and purpose (*e.g.,* potency) in the BLA, and the proposed standard preparations are reviewed by FDA during the regulatory process. The standard preparations may include standard preparations developed by the applicant as well as appropriate standard preparations that can be obtained from other sources. Consistent with current practice, CBER will continue to make and supply standard preparations when appropriate, as well as continue to collaborate with external organizations in the development and assessment of physical standard preparations for licensed biological products.

We are proposing to remove § 610.21 because these potency limits are best described in the BLAs on a product specific basis. Applicants for biological product licenses already identify standards for potency to help ensure the safety, purity, and potency of the product and purpose within their BLA, and the proposed standards are reviewed by FDA during the regulatory process. The use of a potency limit is suitably described in the specific product's BLA and allows for its continued and appropriate use in the absence of § 610.21.

We are proposing to revise § 610.50 by making a minor amendment to the section heading, removing the current language, redesignating § 610.53(b) as § 610.50(a) with edits, revising § 610.50(b), and adding new § 610.50(c). Current § 610.53(b), which applies to all biological products, would be moved to § 610.50(a) and edits will be made for better organization and clarification. Section 610.50(b) would be revised and § 610.50(c) would be added to clarify how the date of manufacture is set for purposes of determining the dating period for general biological products and for Whole Blood and blood components, respectively.

We are proposing to amend the section heading of § 610.53 to reflect that it would only address dating periods for Whole Blood and blood components. We are proposing to revise § 610.53(a) since this section would only apply to the dating periods for Whole Blood and blood components. We are proposing to redesignate current § 610.53(c) as § 610.53(b) and revise the text to provide an explanation on using the table and to correspond with 21 CFR 606.121(c)(7). We are proposing to revise the text and table to eliminate those products for which storage periods, storage conditions, and dating periods are better established by data

submitted in the BLA, and to delete those products which are no longer manufactured. The dating period and storage conditions for these products would be identified in the BLA. We are proposing to include an updated list of Whole Blood and blood component products with their applicable storage temperatures and dating periods, which are based upon available information, including data relating to the anticoagulant or preservative solution in the product, usage, clinical experience, laboratory testing, or further processing. The proposed table contains a list of storage temperatures and dating periods for Whole Blood and blood components that FDA has reviewed and determined to be necessary to help ensure the safety, potency, and purity of these products. In listing the dating periods for the Whole Blood and blood component products, we took into account existing guidance documents, package inserts for solutions used for manufacture or storage of Whole Blood and blood components, and operator instruction manuals for devices used in the manufacture of Whole Blood and blood component products. We are proposing to redesignate § 610.53(c) as § 610.53(b) and to remove all products regulated by FDA's Center for Drug Evaluation and Research (CDER) from the table. Finally, we are proposing to remove § 610.53(d) because it is duplicative of § 640.120.

V. Legal Authority

FDA is issuing this proposed rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the introduction, transmission, and spread of communicable disease.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would remove regulations and revise regulations to be consistent with updated practice, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in part 610 have been approved under OMB control number 0910–0338. The proposed removal of § 610.53(d) would impact OMB control number 0910–0338. We would remove § 610.53(d) because it is duplicative of § 640.120, which is also approved under the same collection of information. While there would be no net change in the burden estimate, the current approved collection of information would be updated to reflect this removal. The actions that we propose to take in this proposed rule would not create a substantive or material modification to this approved collection of information. Therefore, FDA tentatively concludes that OMB has already approved the information collection proposed here and the proposed requirements in this document are not subject to additional review by OMB.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 610 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

Subpart C [Removed and Reserved]

■ 2. Remove and reserve subpart C, consisting of §§ 610.20 and 610.21.

■ 3. Revise § 610.50 to read as follows:

§ 610.50 Date of manufacture for biological products.

(a) When the dating period begins. The dating period for a product must begin on the date of manufacture as described in paragraphs (b) and (c) of this section. The dating period for a combination of two or more products must be no longer than the dating period of the component with the shortest dating period.

(b) Determining the date of manufacture for biological products other than Whole Blood and blood components. The date of manufacture for biological products, other than Whole Blood and blood components, must be identified in the approved

biologics license application as one of the following, whichever is applicable: The date of:

(1) Potency test or other specific test as described in a biologics license application or supplement to the application;

(2) Removal from animals or humans

(3) Extraction;

(4) Solution;

(5) Cessation of growth;

(6) Final sterile filtration of a bulk solution;

(7) Manufacture as described in part 660 of this chapter; or

(8) Other specific manufacturing activity described in a biologics license application or supplement to the biologics license application.

(c) Determining the date of manufacture for Whole Blood and blood components. (1) The date of manufacture for Whole Blood and blood components must be one of the following, whichever is applicable:

(i) Collection date and/or time;

(ii) Irradiation date;

(iii) The time the red blood cell product was removed from frozen storage for deglycerolization;

(iv) The time the additive or rejuvenation solution was added;

(v) The time the product was entered for washing or removing plasma (if prepared in an open system);

(vi) As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA; or

(vii) As approved by the Director, Center for Biologics Evaluation and Research, in a biologics license application or supplement to the application.

(2) For licensed Whole Blood and blood components, the date of manufacture must be identified in the approved biologics license application or supplement to the application.

■ 4. Revise § 610.53 to read as follows:

§ 610.53 Dating periods for Whole Blood and blood components.

(a) *General.* Dating periods for Whole Blood and blood components are specified in the table in paragraph (b) of this section.

(b) *Table of dating periods.* In using the table in this paragraph, when a product in column A is stored at the storage temperature prescribed in column B, storage of a product must not exceed the dating period specified in column C, unless a different dating period is specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA. Container labels for each product must include the recommended storage temperatures.

WHOLE BLOOD AND BLOOD COMPONENTS STORAGE TEMPERATURES AND DATING PERIODS

A	B	C
Product	Storage temperature	Dating period
Whole Blood		
ACD, CPD, CP2D	Between 1 and 6 °C	21 days from date of collection.
CPDA–1	.....do [1]	35 days from date of collection.
Red Blood Cells		
ACD, CPD, CP2D	Between 1 and 6 °C	21 days from date of collection.
CPDA–1	.....do	35 days from date of collection.
Additive solutions	.....do	42 days from date of collection.
Open system (*e.g.,* deglycerolized, washed)	.....do	24 hours after entering bag.
Deglycerolized in closed system with additive solution added.	.....do	14 days after entering bag.
Irradiated	.....do	28 days from date of irradiation or original dating, whichever is shorter.
Frozen	−65 °C or colder	10 years from date of collection.
Platelets		
Platelets	Between 20 and 24 °C	5 days from date of collection.
Platelets	Other temperatures according to storage bag instructions.	As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA.
Plasma		
Fresh Frozen Plasma	−18 °C or colder	1 year from date of collection.
Plasma Frozen Within 24 Hours After Phlebotomy.	.....do	1 year from date of collection.
Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up To 24 Hours After Phlebotomy.	.....do	1 year from date of collection.
Plasma Cryoprecipitate Reduced	.....do	1 year from date of collection.
Plasma	.....do	5 years from date of collection.
Liquid Plasma	Between 1 and 6 °C	5 days from end of Whole Blood dating period.
Source Plasma (frozen injectable)	−20 °C or colder	10 years from date of collection.
Source Plasma Liquid (injectable)	10 °C or colder	According to approved biologics license application.
Source Plasma (noninjectable)	Temperature appropriate for final product	10 years from date of collection.
Therapeutic Exchange Plasma	−20 °C or colder	10 years from date of collection.

WHOLE BLOOD AND BLOOD COMPONENTS STORAGE TEMPERATURES AND DATING PERIODS—Continued

A	B	C
Product	Storage temperature	Dating period
Cryoprecipitated AHF		
Cryoprecipitated AHF	−18 °C or colder	1 year from date of collection of source blood or from date of collection of oldest source blood in pre-storage pool.
Source Leukocytes		
Source Leukocytes	Temperature appropriate for final product	In lieu of expiration date, the collection date must appear on the label.

[1] The abbreviation "do." for ditto is used in the table to indicate that the previous line is being repeated.

Dated: April 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10386 Filed 5–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 982

[Docket No. FR–5928–N–01]

Notice of Demonstration To Test Proposed New Method of Assessing the Physical Conditions of Voucher-Assisted Housing

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: Through this document, HUD solicits comment on a demonstration designed to test a new method of assessing the physical condition of housing assisted by HUD vouchers (voucher-assisted housing). In the Joint Explanatory Statement accompanying the act appropriating funds for HUD in Fiscal Year (FY 2016), Congress directed HUD to implement a single inspection protocol for public housing and voucher units. This demonstration would commence the process for implementing a single inspection protocol.

DATES: *Comments Due Date:* July 5, 2016.

ADDRESSES: Interested persons are invited to submit comments to the Office of the General Counsel, Regulations Division, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications should refer to the above docket number and title and should contain the information specified in the "Request for Comments" section. There are two methods for submitting public comments.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at all federal agencies, however, submission of comments by mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that comments submitted by mail be submitted at least two weeks in advance of the public comment deadline.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted using one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Comments. All comments and communications submitted to HUD will be available, for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel R. Williams, Real Estate Assessment Center, Office of Public and Indian Housing, Department of Housing and Urban Development, 550 12th Street SW., Suite 100, Washington DC 20410–4000; telephone number 202–475–8586 (this is not a toll-free number). Persons with hearing or speech impairments may contact this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Structure of the Notice

The following four sections discuss the background through the solicitation of comments. Section II below provides background information on oversight of the Housing Choice Voucher inspection program and explains the origins of the Uniform Physical Condition Standards for Vouchers (UPCS–V), an alternative approach for ensuring safe, habitable voucher-assisted housing. In Section III, the notice explains the three main areas that will be evaluated during the demonstration, which are: The objective condition standards including a list of life threatening and emergency items that must be addressed, the revised information technology (IT) processes, and the new oversight approach. Also in Section III, HUD discusses the general public housing agency (PHA) participation criteria it will use to select a representative mix of volunteer PHAs. In Section IV, HUD describes the process by which HUD will assess the results of the demonstration. In the last section of this notice, Section V, HUD