''Accomplishment Timescale,'' of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, except as required by paragraph (l)(1) of this AD.

(2) Do all applicable repetitive inspections of the restored and repaired areas at the applicable intervals specified in Tables 3, 4A, 4B, 4C, 4D, and 5 in paragraph 1.E.(2), ''Accomplishment Timescale,'' of Airbus Service Bulletin A320–55–1041, dated November 26, 2012.

(k) Airplanes Excluded From Certain Requirements

Airplanes fitted with a rudder having a serial number which is not in the range TS–1001 to TS–1639 inclusive, or TS–2001 to TS–5890 inclusive; or is not TS–5927; are not affected by the requirements of paragraphs (h), (i), and (j) of this AD, provided it is determined that no repairs have been done as described in the structural repair manual (SRM) procedures identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of Airbus Service Bulletin A320–55–1041, dated November 26, 2012, on the composite side shell panel of that rudder since first installation on an airplane.

(l) Exception to Service Information

(1) Where the service bulletin specifies a compliance time ''after the original Service Bulletin issue date,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) If any damage or fluid ingress is found during any inspection required by this AD and Airbus Service Bulletin A320–55–1041, dated November 26, 2012, specifies to contact Airbus: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Parts Installation Limitation

As of the effective date of this AD, in case of rudder replacement, it is allowed to install a rudder on an airplane, provided that prior to installation the rudder is determined to be compliant with the requirements of paragraphs (h), (i), (j), and (k) of this AD.

(n) Repair Prohibition

As of the effective date of this AD, do not accomplish a composite side shell panel repair on any rudder using an SRM procedure identified in Figure A–GBBAA (Sheet 01 and 02) or Figure A–GBCAA (Sheet 02) of Airbus Service Bulletin A320–55–1041, dated November 26, 2012.

(o) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov.* 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. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2013–0302, dated December 19, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0574.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on August 15, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–19979 Filed 8–21–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 610 and 680

[Docket No. FDA–2014–N–1110]

Revocation of General Safety Test Regulations That Are Duplicative of Requirements in Biological License Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by removing the general safety test (GST) requirements for biological products. FDA is proposing this action because the existing codified GST regulations are duplicative of requirements that are also specified in biologics licenses, or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products. FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation, in response to an Executive order.

DATES: Submit either electronic or written comments on this proposed rule by November 20, 2014. See section V of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

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

Instructions: All submissions received must include Docket No. FDA–2014–N–

1110 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading in section X of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or 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: Lori J. Churchyard, 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:

Executive Summary

Purpose and Coverage of the Proposed Rule

The proposed rule would eliminate the codified GST [1] regulations for biological products. FDA is proposing this action because the existing codified GST regulations 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. FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation, in response to Executive Order (E.O.) 13563 of January 18, 2011.

Summary of the Major Provisions of the Proposed Rule

The proposed rule would remove the requirements contained in 21 CFR 610.11, 610.11a, and 680.3(b) from the regulations. Section 610.11 concerns a GST for the detection of extraneous toxic contaminants in biological products intended for administration to humans. Section 610.11a concerns the GST regulations for inactivated influenza vaccine. Section 680.3(b) concerns GST regulations for allergenic products. Removal of these regulations would not remove GST requirements specified in individual BLAs, however. A biological product manufacturer would continue to be required to follow the GST requirements specified in its BLA unless the BLA were revised to eliminate or modify the test through a supplement in accordance with 21 CFR 601.12(c). FDA would review proposed changes to a manufacturer's approved biologics license on a case-by-case basis so that we could ensure that any such action is appropriate.

Costs and Benefits

FDA is proposing this action because the existing codified GST regulations are duplicative of requirements that are also specified in BLAs, or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products. Because this proposed rule would impose no additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

I. Background

On January 18, 2011, President Barack Obama issued E.O. 13563, ''Improving Regulation and Regulatory Review'' (76 FR 3821, January 21, 2011). One of the provisions in the E.O. is the affirmation of retrospective reviews of existing significant regulations. As one step in implementing the new E.O., FDA published a notice in the **Federal Register** on 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 eliminate the codified GST regulations as specified in this rule. We believe this action is appropriate because in many instances, the GST regulations duplicate requirements that are also specified in the BLA required for biological products intended for human use under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), or they are outmoded or otherwise unnecessary to help ensure the continued safety, purity, and potency of biological products. For a number of years, FDA has not codified specific requirements for licensed biological products, in part because codifying specific requirements for biological products can diminish the ability of the Agency and industry to respond to technological developments. Instead the Agency has described the required tests for particular products in manufacturers' BLAs.

The GST is one of several tests listed in part 610, General Biological Product Standards, that is intended to help ensure the safety, purity, and potency of biological products administered to humans. Manufacturers of biological products are currently required to perform this test for general safety on biological products intended for administration to humans under § 610.11, on inactivated influenza vaccines under § 610.11a, and on allergenic products under § 680.3(b), unless exempted by regulation or an exemption is granted under § 610.11(g)(2).

The GST was intended to be a final check designed to detect any toxic contaminants present in the final product. The test was cited as early as 1909 (Ref. 1), and appeared in the first Code of Federal Regulations in 1938, before the establishment of Current Good Manufacturing Practices (cGMPs) for drug manufacture in the CFR, which occurred in 1963. The GST was subsequently revised to, among other things, ''reflect the best current testing procedures established by the scientific community as well as to promote uniformity and specificity in the safety testing of licensed biological products'' (March 15, 1976, 41 FR 10888).

A product that meets the requirements for general safety will comply with the criteria found in § 610.11(d) of the GST regulation, i.e., injected animals survive the test period; they do not exhibit any response that is not specific for or expected from the product and which may indicate a difference in quality of the product; and they weigh no less at the end of the test period than they did at the time of injection.

While originally a useful approach, as time has passed, the Agency has periodically explored the utility and efficiency of this approach. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA published a final rule exempting certain biotechnology-derived and synthetic biological products from a number of regulations applicable to biological products, including the GST (see § 601.2(c)). This action was in response to technical advances that greatly increased the ability of manufacturers to control the manufacture of, and to more fully analyze the physical and biological characteristics of, many biotechnology-derived biological products.

[1] For purposes of this proposed rulemaking, the terms ''general safety test'' or ''GST'' refer to the requirements found under Title 21 of the Code of Federal Regulations (CFR), subchapter F, parts 600 through 680 (21 CFR parts 600 through 680), specifically 21 CFR 610.11, 21 CFR 610.11a and 21 CFR 680.3(b).

Approximately 2 years later, in the **Federal Register** of April 20, 1998, FDA issued a direct final rule (DFR) and a companion proposed rule (63 FR 19399 and 19431, respectively) to expand the exceptions in § 610.11(g) to include ''cellular therapy products'' because, among other reasons, the Agency believed that the procedures and materials used to manufacture these products are stringently controlled and monitored. In addition, FDA provided for in the DFR and the companion proposed rule an administrative procedure for manufacturers of other biological products to request and obtain exemptions from conducting the GST. FDA took this action ''. . . because the GST may not be relevant or necessary for biological products . . . currently in various stages of development'' and as part of FDA's continuing efforts at that time ''to reduce the burden of unnecessary regulations on biological products without diminishing the protection of the public health'' (63 FR 19399 at 19400) (FDA refers readers to the preamble of the April 20, 1998, proposed rule should they wish to obtain additional details on the history of this rulemaking).

In the **Federal Register** of August 5, 1998 (63 FR 41718) (August 1998 Notice), FDA published a DFR confirming in part, and withdrawing in part, the provisions in the DFR that published April 20, 1998. Specifically, FDA confirmed a revision to § 610.11(g)(1) to add ''cellular therapy products'' to the list of products exempted from the GST. However, because the Agency received significant adverse comments concerning § 610.11(g)(2), the provision of the rule that required administrative procedures for requesting an exemption from the GST regulations, § 610.11(g)(2) was withdrawn. As discussed in the August 1998 Notice, the comments were applied to the corresponding portion of the companion proposed rule and considered in developing the final rule.

After considering the comments to the DFR and companion proposed rule, in the **Federal Register** of March 4, 2003 (68 FR 10157 at 10158) (March 2003 Final Rule), FDA again provided for an administrative procedure under which manufacturers of biological products may request and obtain exemptions from conducting the GST (§ 610.11(g)(2)). In the preamble to the March 2003 Final Rule, FDA again noted that the GST may not be relevant or necessary for certain biological products (68 FR 10157).

Accordingly, § 610.11 currently includes a provision allowing manufacturers to request an exemption from the GST. Note that this exemption provision requires manufacturers to provide supporting documentation when making their request (see 68 FR 10157 through 10159). Specifically, when requesting such an exemption, manufacturers must submit information as part of a BLA or supplement to an approved BLA establishing that because of the mode of administration, the method of preparation, or the special nature of the product, a test for general safety is unnecessary to assure the safety, purity, and potency of the product, or cannot be performed (§ 610.11(g)(2)).

Since FDA issued the March 2003 Final Rule, it has become increasingly clear that the codified GST regulations are too restrictive for certain additional biological products because they specify particular methodologies or requirements when alternatives may be available that provide the same or greater level of assurance of safety. Thus, the Agency believes that the regulations may no longer reflect the best current testing procedures established by the scientific community as a general matter (although the testing procedures may still be appropriate in certain circumstances) and that the more efficient way of prescribing testing requirements for particular products would be to allow such requirements to be specified in the BLA to enhance flexibility to make appropriate changes to testing methods.

II. Appropriate Controls Would Remain in Place

FDA believes that if this rulemaking becomes finalized as proposed, we would be able to continue to ensure that appropriate controls remain in place. For example, manufacturers of all products derived from inherently toxic substances would be required to continue to use the safety tests that are prescribed in their BLAs to control and monitor toxicity. These product-specific tests (performed in animals, cell cultures, or other systems) in conjunction with physical, chemical, and biological characterization tests define and monitor the production process and alert manufacturers to potential problems. Because these tests are tailored to the proprietary manufacturing process and are appropriate for the detection of intrinsic or extraneous toxic contaminants for a particular product or product class, they are more appropriately specified in the manufacturer's BLA or BLA supplement than codified as regulations.

Furthermore, we anticipate that the proposal to eliminate the codified GST regulations would encourage the implementation of the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing, thus addressing the need to minimize the use of animals in such testing and promoting more humane, appropriate, and specific test methods for assuring the safety of biological products.[2]

If the proposed rule is finalized and the GST regulations are eliminated, manufacturers would continue to be required to perform a particular safety test for certain products that present specific safety concerns, for example, testing for a specific toxicity, as set forth in an approved BLA or BLA supplement. As discussed previously, although this rulemaking proposes to eliminate the codified GST from the biologics regulations, FDA recognizes that all manufacturers that currently conduct a GST have this test described in their BLAs for their licensed products. As a result, if this proposed rule is finalized, these manufacturers would continue to be required to perform the GST unless the manufacturer's BLA were revised through a supplement to eliminate or modify the test. FDA would review these proposed changes to a manufacturer's approved BLA on a case-by-case basis so that we could ensure that any such action is appropriate. Thus, the removal of these biologics regulations, should this proposed rule be finalized, would not automatically revise a manufacturer's BLA or BLA supplement.

The requirements for a licensed biological product manufacturer to report changes in its product, product labeling, production process, quality controls, equipment, facilities, or responsible personnel, as established in its approved BLA, are detailed in § 601.12. Under this regulation, manufacturers must report each change to the Agency in one of several different types of submissions. The applicable submission category depends on the potential for the change(s) at issue to have an adverse effect on the identity, strength, quality, purity, or potency of the particular biological product as it may relate to the safety or effectiveness of the product. A BLA supplement for a change that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as it may relate to the safety

[2] Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Authorization Act of 2000 (42 U.S.C. 2851–3). Additional information on the Federal Government's implementation of the principles of the 3Rs may be found at the ICCVAM Web site at *http://ntp.niehs.nih.gov/go/iccvam.*

or effectiveness of the product must be submitted under § 601.12(c) (*Changes requiring supplement submission at least 30 days prior to distribution of the product made using the change*).

As a general matter, should a manufacturer wish to no longer perform the GST described in its BLA, the Agency would consider the discontinuation of the GST to have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as it may relate to the safety or effectiveness of the product. Accordingly, a manufacturer who desires to discontinue the GST in the approved BLA or utilize an alternative method other than the GST approved in its BLA must submit a BLA supplement reporting the change in accordance with § 601.12(c). Within 30 days of the date FDA receives the submission, FDA will determine if the change has been reported in the proper category and will notify the manufacturer if it has not. If FDA has not notified the manufacturer otherwise within 30 days after FDA receives the supplement, the manufacturer may distribute its product using the change described in the supplement. If, however, FDA determines that the information submitted in the supplement fails to demonstrate the continued safety or effectiveness of the product made using the change, FDA will try to resolve the problems with the manufacturer. For example, in the event that the Agency determines that for a particular manufacturer's unique product a GST is still necessary to assure the continued safety or effectiveness of the product (e.g., for products with concerns related to residual toxin activity/reversion to toxicity, or if the alternative method proposed is unacceptable), the Agency would notify the manufacturer of its decision within 30 days following receipt of the supplement and would work with the manufacturer to resolve the issue.

III. Highlights of the Proposed Rule

The proposed rule would remove §§ 610.11, 610.11a, and 680.3(b), the regulations that require that manufacturers of biological products perform a specified test for general safety of biological products. FDA is taking this action because the existing codified GST regulations are duplicative, outmoded, or are otherwise unnecessary to help ensure the continued safety, purity, and potency of licensed biological products.

IV. Legal Authority

FDA is issuing this regulation under the biological products provisions of the PHS Act (42 U.S.C. 262 and 264), and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*). 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, effective, pure, and potent, and to prevent the introduction, transmission, and spread of communicable disease.

V. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal be effective 90 days after the date of its publication in the **Federal Register**.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, 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 Agencies 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). The Agency believes that this proposed rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule generally increases flexibility for safety testing and would result in the reduction of certain regulatory burdens and does not add any new regulatory responsibilities, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

This rule proposes to amend the biologics regulations by removing GST regulations for biological products found in §§ 610.11, 610.11a and 680.3(b). FDA is proposing this action because the current codified GST regulations are duplicative of requirements that are also specified in biologics licenses, or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products. The removal of the GST regulations for biological products would not remove GST requirements specified in individual biologics license applications, however. All manufacturers that currently conduct a GST are already required, as part of the requirements specified in their biologics license applications, to perform the GST and would thus continue to be required perform the GST unless the BLA were revised to eliminate or modify the test through a supplement in accordance with § 601.12(c). Because this proposed rule would impose no additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

VII. The Paperwork Reduction Act of 1995

This proposed rule refers to previously approved 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 § 601.12 have been approved under OMB control number 0910–0338. Therefore, FDA tentatively concludes that the proposed requirements in this document are not subject to review by OMB because they do not constitute a ''new collection of information'' under the PRA.

VIII. Environmental Impact

The Agency has determined under 21 CFR 25.30(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.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. FDA has

determined that the proposed rule, if finalized, would not contain policies that would 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, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

X. Request for 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.*

XI. Reference

FDA has placed the following reference on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and are available electronically at *http://www.regulations.gov.*

1. Anderson, J. F., ''The Influence of Concentration (Gibson's Method) On the Presence of Tetanus Toxin in Blood Serum,'' *Journal of Experimental Medicine:* 1909 September 2; 11(5): 656–658.

List of Subjects

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 610 and 680 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for 21 CFR 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.

§ 610.11 [Removed and Reserved]

■ 2. Remove and reserve § 610.11.

§ 610.11a [Removed and Reserved]

■ 3. Remove and reserve § 610.11a.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

■ 4. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 680.3 [Amended]

■ 5. Remove and reserve paragraph (b).

Dated: August 18, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19888 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0522; FRL–9915–48-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Infrastructure Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia pursuant to the Clean Air Act (CAA). Whenever new or revised National Ambient Air Quality Standards (NAAQS) are promulgated, the CAA requires states to submit a plan for the implementation, maintenance, and enforcement of such NAAQS. The plan is required to address basic program elements including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. The Commonwealth of Virginia has made a submittal addressing the infrastructure requirements for the 2010 sulfur dioxide (SO_2) NAAQS.

DATES: Written comments must be received on or before September 22, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2014–0522 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2014–0522, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2014–0522. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the