12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this direct final 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 direct final rule does not impose any additional regulatory burdens, we certify that this direct final 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 issuing ''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 $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This direct final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule is being issued to amend the general biologics regulations by removing time of inspection requirements and the duties of inspector requirements. This action is being taken to remove outdated requirements, accommodate new approaches, and provide flexibility without diminishing public health protections. Because this rulemaking would remove regulations to be consistent with updated practice and does not impose any additional regulatory burdens, this rulemaking is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

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 direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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 direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 600

Biologics, 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, 21 CFR part 600 is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.21 [Amended]

■ 2. Amend § 600.21 by removing the last three sentences.

§ 600.22 [Removed and Reserved]

■ 3. Remove and reserve § 600.22.

Dated: January 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01468 Filed 1–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

[Docket No. FR–6077–I–01]

Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects

AGENCY: Office of the Assistant Secretary for Policy, Development and Research, HUD.

ACTION: Interim final rule; delay of effective and compliance dates; request for comments.

SUMMARY: On January 19, 2017, HUD and other federal departments and agencies published a final rule which revised the Federal Policy for the Protection of Human Subjects (2018 Requirements). Most of the 2018 Requirements were scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018. On January 22, 2018, the Federal departments and agencies that adopted the 2018 Requirements published an interim final rule (''the interagency interim final rule'') that delays the effective date and general compliance date of the 2018 Requirements for six months, to July 19, 2018. The purpose of the delay is to provide additional time to regulated entities for the preparations necessary to implement the 2018 requirements. Due to statutory prepublication requirements applicable to HUD rules, HUD was unable to be a signatory to the interagency interim final rule. Through this interim final rule, HUD adopts the interagency interim final rule.

DATES: *Effective date:* February 26, 2018.

Comment due date: March 27, 2018.

ADDRESSES: You may submit comments, identified by docket ID number HHS–OPHS–2017–0001 by one of the following methods:

- *Federal eRulemaking Portal (http://www.regulations.gov):*
  - Enter the following link into your web browser's address bar: *https://www.regulations.gov/document?D=HHS-OPHS-2017-0001.*
  - Click the blue ''Comment Now!'' button in the upper right-hand corner and follow the instructions on how to submit a comment.
  - Alternatively, you can enter the docket ID number into the ''search'' box on the main page of the Federal eRulemaking Portal (*http://www.regulations.gov*) to find the electronic docket.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]*

to: Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

• Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Barry L. Steffen, Policy Development Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street SW, Room 8114, Washington, DC 20410–8000, telephone 202–402–5926. (This is not a toll-free number.) Persons with hearing- or speech-impairments may access this number through TTY number by calling the Federal Relay Service number at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On January 19, 2017, HUD and other Federal departments and agencies that are subject to the Federal Policy for the Protection of Human Subjects published a final rule amending that policy (82 FR 7149) (2018 Requirements). The Department of Health and Human Services (HHS) is the lead agency on this rulemaking. The 2018 Requirements were scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018 (with the exception of the revisions to the cooperative research provision at 24 CFR 60.114(b), for which the compliance date is January 20, 2020). After publication of the 2018 Requirements, representatives of the regulated community expressed concern regarding their ability to implement all of the 2018 Requirements by the scheduled general compliance date and some asked for a delay. The HHS Secretary's Advisory Committee on Human Research Protections recommended in August 2017 that the required implementation of the 2018 Requirements be delayed.

On January 22, 2018, at 83 FR 2885, the Federal departments and agencies published an interagency interim final rule, which delays the effective date and general compliance date of the 2018 Requirements for six months, to July 19, 2018. The interagency interim final rule also solicits public comment on whether changes to the rule are justified. Due to statutory prepublication requirements applicable to HUD rules, HUD was unable to be a signatory to the interagency interim final rule. Specifically, section 7(o) the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)) provides for 15-day Congressional prepublication review of certain HUD rules. Rather than potentially delay publication of the interagency rule to comply with this HUD-specific requirement, HUD has opted to issue this interim final rule. HUD's rule adopts the interagency interim final rule and also solicits public comment on whether changes to the effective and compliance dates are justified. Please see the interagency interim final rule for further background and explanation.

II. Justification for Interim-Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advanced notice and public participation. The good cause requirement is satisfied when prior public procedure is ''impractical, unnecessary, or contrary to the public interest'' (see 24 CFR 10.1). For the following reasons, HUD has determined that it would be contrary to the public interest to delay the effectiveness of this rule in order to solicit prior public comments.

The rule does not substantively alter the requirements of the 2018 Requirements, which were issued following advance notice and an opportunity for comment. Rather, the sole purpose of this rulemaking is to delay the effective date and general compliance date of those requirements. As noted, the delay is being issued in response to concerns from the public. HUD is issuing this rule separately from the other agencies due to statutory prepublication review requirements. A delay for prior public procedure would result in HUD program participants being subject to a unique set of regulatory requirements different than those applicable for other, substantially identical, Federal activities. Participants in programs administered by HUD as well as those of other agencies would be required with two different set of regulations for undertaking similar activities.

Given the burdensome outcomes resulting from a delay, the non-substantive nature of the rule, and the fact that the rule responds to concerns raised by the public, HUD believes that good cause exists to publish this rule for effect without prior public comment. HUD, however, recognizes the value of public comment in the development of its regulations. HUD has, therefore, issued these regulations on an interim basis and has provided the public with a 60-day comment period. HUD welcomes comments on the regulatory amendments made by this interim rule. The public comments will be addressed in the final rule.

III. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' For further discussion of the significance of this interim final rule and its anticipated benefits and costs, see the interagency interim final rule.

Paperwork Reduction Act (PRA)

This interim final rule does not impose any additional information collection burden under the PRA. If finalized, this interim final rule will not contain any information collection activities beyond the information collection already approved by OMB under control number 0990–0260.

Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This interim final rule does not impose a regulatory burden for regulated small entities because it delays the effective date and the general compliance date of the 2018 Requirements, allowing the status quo to be retained for the period of delay. Therefore, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact

This interim final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or

construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. 4321).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This interim final rule does not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of UMRA.

Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either (1) imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or (2) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This interim final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs was issued on January 30, 2017. For further discussion of E.O. 13771, please see the interagency interim final rule.

List of Subjects for 24 CFR Part 60

Human research subjects, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends part 60 of title 24 of the Code of Federal Regulations as follows:

PART 60—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b) and 3535(d).

■ 2. Amend § 60.101 by revising paragraphs (l)(3) and (4) to read as follows:

§ 60.101 To what does this policy apply?

* * * * *

(l) * * *

(3) Research initially approved by an IRB, for which such review was waived pursuant to § 60.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to § 60.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

* * * * *

Dated: January 11, 2018.

Todd M. Richardson,

Acting General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2018–01497 Filed 1–25–18; 8:45 am]

BILLING CODE 4210–67–P

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 517

RIN 3141–AA21

Freedom of Information Act Procedures

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: This rule amends the procedures followed by the National Indian Gaming Commission when processing a request under the Freedom of Information Act, as amended. These amendments update certain Commission information, conform to changes made in the Freedom of Information Act Improvements Act of 2016, and streamline how the Commission processes its Freedom of Information Act requests.

DATES: This rule is effective on February 26, 2018.

FOR FURTHER INFORMATION CONTACT: Tana Fitzpatrick at (202) 632–7003 or by fax (202) 632–7066 (these numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Background

In 1966, Congress enacted the Freedom of Information Act (FOIA). Later, on October 17, 1988, Congress enacted the Indian Gaming Regulatory Act (IGRA), which established the National Indian Gaming Commission (Commission). On August 23, 1993, the Commission adopted FOIA procedures and, on April 19, 2006, subsequently amended its FOIA procedures. Since that time, the United States Congress has amended the FOIA twice, and the Commission has changed the location of its headquarters office and streamlined the way it processes its FOIA requests.

On October 17, 2017, the Commission published a proposed rule (82 FR 48205) that proposed changes to the Commission's regulations and requested public comments for 30 days. This final rule implements the proposed changes and responds to public comments received on the proposed rule. This rule updates the location of the Commission's headquarters, conforms to changes made in the FOIA Improvements Act of 2016, and streamlines how the Commission processes its FOIA requests.

II. Contents of Final Rule

This rule finalizes updates in each section of the Commission's FOIA regulations. Under 25 CFR 517.1, *General provisions,* the Commission incorporates revisions providing that requests for information under this part may also be simultaneously processed under the Privacy Act regulation under 25 CFR part 515. Additionally, under 25 CFR 517.2, *Public reading room,* the Commission updates its headquarters to its new address.

This rule also updates certain definitions under 25 CFR 517.3 to conform to case law and statutory requirements. The Commission made the following changes:

(1) Changed definition of 'record.' The Commission revised the definition because the present definition of 'record' is too narrow based on the Supreme Court's interpretation of what constitutes a 'record' under FOIA;

(2) Expanded 'representatives of the news media' to comport with the FOIA's definition;