XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the final rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment.'' **Federal Register** (Docket No. FDA–2016–N–1487). Online November 29, 2016. *https://www.federalregister.gov/documents/2016/11/29/2016-28582/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment.*
2. FDA. Submission of Food and Drug Administration Import Data in the Automated Commercial Environment (Final Rule) Regulatory Impact Analysis. Economic Impact Analyses of FDA Regulations. Online November 29, 2016. *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*
3. FDA. Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS). 2015–2017 data.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. Amend § 1.71 by adding in alphabetical order the definition for ''Veterinary device'' to read as follows:

§ 1.71 Definitions.

* * * * *

Veterinary device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in animals.

■ 3. Revise § 1.72 introductory text to read as follows:

§ 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

General. When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, veterinary devices, radiation-emitting electronic products, cosmetics, and tobacco products.

* * * * *

■ 4. Revise § 1.75 to read as follows:

§ 1.75 Animal drugs and veterinary devices.

(a) *Animal drugs.* In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(1) *Registration and listing.* For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE at the time of entry is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(2) *New animal drug application number.* For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(3) *Veterinary minor species index file number.* For a drug intended for use in animals that is the subject of an Index listing under section 572 of the Federal Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(4) *Investigational new animal drug file number.* For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug file under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

(b) *Veterinary devices.* An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE for veterinary devices.

Dated: October 6, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

In concurrence with FDA.

Dated: October 6, 2022.

Thomas C. West, Jr.,

Deputy Assistant Secretary of the Treasury for Tax Policy, Department of the Treasury.

[FR Doc. 2022–22532 Filed 10–17–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 518

RIN 3141–AA72

Self-Regulation of Class II Gaming

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC) is amending its regulations regarding self-regulation of Class II gaming under the Indian Gaming Regulatory Act. The amendment revises the regulations to address an ambiguity in the petitioning process and clarifies the Office of Self-Regulation's (OSR) role once the Commission issues a certificate. Notably, the amendment: Clarifies the NIGC may issue a final decision on issuing a certificate within 30 days instead of after 30 days; removes the requirement that the director of the OSR must be a Commissioner; enumerates the OSR is the correct party to receive notifications of material changes from self-regulated tribes; expands the deadline for tribes to report material changes to the OSR from three business days to 10 business days; clarifies the OSR will be the office to make any recommendations to revoke a certificate of self-regulation before the Commission; and clarifies that, in any revocation proceeding, the OSR has the burden to show just cause for the revocation and carry that burden by a preponderance of the evidence.

DATES: Effective November 17, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, National Indian Gaming Commission; 1849 C Street NW, MS 1621, Washington, DC 20240. Telephone: (202) 632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission (NIGC or Commission) and sets out a comprehensive framework for the regulation of gaming on Indian lands.

On January 31, 2012, the Commission published a notice of proposed rulemaking to promulgate part 518, the procedures controlling self-regulation. 77 FR 4714 (Jan. 31, 2012). Once promulgated, part 518 established the procedures for the Commission and the OSR to, among other things, receive, evaluate, recommend, issue, deny, or revoke a certificate of self-regulation. On September 1, 2013, after initial publication, the Commission enacted minor revisions to part 518 to amend certain timelines and an incorrect section heading and reference to IGRA. 78 FR 37114 (Sept. 1, 2013).

II. Development of the Proposed Rule

On June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the procedures controlling self-regulation. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendments are intended to improve the Agency's efficiency in evaluating petitions for self-regulation, reduce the time it takes to obtain a certificate of self-regulation, and clarify the Office of Self-Regulation's functions.

The Commission held two virtual consultation sessions in September and one virtual consultation in October of 2021 to receive tribal input on any proposed changes. After considering the comments received from the public and through tribal consultations, the Commission published a notice of proposed rulemaking on April 7, 2022, 87 FR 20351. The notice of proposed rulemaking indicated that comments were due on or before June 6, 2022. On June 16, 2022, 87 FR 36280, the NIGC announced the reopening of the comment period until June 23, 2022.

The Commission reviewed all of the public's comments and now adopts these changes, which it believes will improve the self-regulation process.

III. Review of Public Comments

The Commission received the following comments in response to the notice of proposed rulemaking.

Comment: Several commenters approved of the change that clarified the Commission may issue a final determination for a certificate of self-regulation within 30 days if no hearing is requested, as the prior language was ambiguous and potentially left open an indefinite time period for a determination.

Response: The Commission appreciates the comment and has left the language in the final rule.

Comment: Several commenters approved of the change from three to ten business days for tribes to notify the OSR of material changes.

Response: The Commission appreciates the comment and has left the language in the final rule.

Comment: Several commenters approved that placing the burden of proof on the OSR in revocation hearings.

Response: The Commission appreciates these comments and has left the language in the final rule.

Comment: A commenter stated that procedural questions were left unanswered for § 518.7(f), specifically (1) to whom should the notice be directed, (2) what restrictions exist to who may send a notice, and (3) the contents of the notice and what it must include.

Response: The Commission appreciates the comment and intends to provide clarity on these and other process questions. It does not wish, however, to codify a process that may change in the future. The Commission intends to publish guidance for administrative and procedural matters on its website where it can be updated as needed.

Comment: Numerous commenters expressed concern with the reporting requirements in § 518.11 and commented that there were unanswered questions as to what needs to be reported.

Response: The Commission appreciates the comments, and notes that the only proposed change to the rule pertained to the office the Tribe or Tribal Gaming Regulatory Authority reports such information. The Commission believes the scope of what needs to be detailed is sufficiently covered by the reference to § 518.5, which does specify criteria that will be considered by the Commission when deciding to grant a certificate of self-regulation, as well as the examples given in § 518.11. To the extent that additional guidance or detail is needed, the Commission will include such information in future bulletins.

Comment: Several commenters expressed concern that if a Commissioner is appointed the head of the OSR they would be the proponent of any case to revoke a certificate before the Commission and also voting on the revocation. The commenters stated that this would create an insurmountable conflict of interest.

Response: The Commission has changed the rule to no longer require that a Commissioner serve as the head of the OSR. That being said, there is nothing to prohibit the Commission from appointing a Commissioner to lead the office, and the Commission disagrees with the commenter's assertion that a Commissioner serving as head of the OSR would create a conflict of interest. It is not a violation of due process for the Commissioners to serve both investigatory and adjudicatory functions. The United State Supreme Court held as much in the case *Withrow* v. *Larkin,* 421 U.S. 35, 51–52 (1975), following the cases that rejected the idea that the combination (of) judging (and) investigating functions is a denial of due process. The Court further stated there is a presumption of honesty and

integrity in those serving as adjudicators. Moreover, the NIGC is familiar with such a structure and the dual role of investigator and adjudicator comes from IGRA itself. Section 2706 of IGRA tasks the Commission with investigatory and inspection powers, while section 2713 requires the Commission to hear any appeals of a civil fine or closure order issues by the Chairman. The Commission has long worked under such a structure. For example, the Chairman makes a determination on a gaming ordinance and also sits on the panel if it is appealed. And although there is a presumption of fairness, the NIGC nevertheless has policies and procedures in place to ensure a fair decision on all appeals and investigations.

Comment: A commenter requested that if a commissioner is appointed as Director of OSR that they recuse themselves from participating as a Commissioner of NIGC in revocation hearings for due process concerns.

Response: The Commission declines to adopt this suggestion for the same reason as above.

Comment: Several comments were outside the scope of the rulemaking and related generally to the self-regulation process, the lack of guidance and the inability of more tribes to participate in the self-regulation process.

Response: The Commission appreciates these comments and will take them into consideration for future guidance or amendments to the rule.

IV. Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian tribes are not considered small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions. Nor will the rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of section 3(a) and 3(b)(2) of the order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501 *et seq.* and assigned OMB Control Number 3141–0003.

Tribal Consultation

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order (E.O.) 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published July 15, 2013. The NIGC consultation policy specifies that it will consult with tribes on Commission Actions with Tribal Implications, which is defined as: Any Commission regulation, rulemaking, policy, guidance, legislative proposal, or operational activity that may have a substantial direct effect on an Indian tribe on matters including, but not limited to the ability of an Indian tribe to regulate its Indian gaming; an Indian tribe's formal relationship with the Commission; or the consideration of the Commission's trust responsibilities to Indian tribes.

Pursuant to this policy, on June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on a number of topics, including proposed changes to the self-regulation process.

List of Subjects in 25 CFR Part 518

Gambling, Indian—lands, Indian—tribal government, Reporting and recordkeeping requirements.

Therefore, for reasons stated in the preamble, 25 CFR part 518 is amended as follows:

PART 518—SELF-REGULATION OF CLASS II GAMING

■ 1. The authority citation for part 518 is revised to read as follows:

Authority: 25 U.S.C. 2706(b)(10); 25 U.S.C. 2710(c).

■ 2. Revise § 518.2 to read as follows:

§ 518.2 Who will administer the self-regulation program for the Commission?

The self-regulation program will be administered by the Office of Self–Regulation. The Chair shall appoint a Director to administer the Office of Self–Regulation.

■ 3. Revise § 518.5(b) introductory text to read as follows:

§ 518.5 What criteria must a tribe meet to receive a certificate of self-regulation?

* * * * *

(b) A tribe may illustrate that it has met the criteria listed in paragraph (a) of this section by addressing factors such as those listed in paragraphs (b)(1) through (9) of this section. The list of factors is not all-inclusive; other factors not listed here may also be addressed and considered.

* * * * *

■ 4. Revise § 518.7(f) to read as follows:

§ 518.7 What process will the Commission use to review and certify petitions?

* * * * *

(f) The Commission shall issue a final determination within 30 days after issuance of its preliminary findings if the tribe has informed the Commission in writing that the tribe does not request a hearing or within 30 days after the conclusion of a hearing, if one is held. The decision of the Commission to approve or deny a petition shall be a final agency action.

* * * * *

■ 5. Revise § 518.11 to read as follows:

§ 518.11 Does a tribe that holds a certificate of self-regulation have a continuing duty to advise the Commission of any additional information?

Yes. A tribe that holds a certificate of self-regulation has a continuing duty to

advise the Office of Self-Regulation within 10 business days of any changes in circumstances that are material to the approval criteria in § 518.5 and may reasonably cause the Commission to review and revoke the tribe's certificate of self-regulation. Failure to do so is grounds for revocation of a certificate of self-regulation. Such circumstances may include, but are not limited to, a change of primary regulatory official; financial instability; or any other factors that are material to the decision to grant a certificate of self-regulation.

■ 4. Revise §§ 518.13 and 518.14 to read as follows:

§ 518.13 When may the Commission revoke a certificate of self-regulation?

If the Office of Self-Regulation determines that the tribe no longer meets or did not comply with the eligibility criteria of § 518.3, the approval criteria of § 518.5, the requirements of § 518.10, or the requirements of § 518.11, the Office of Self-Regulation shall prepare a written recommendation to the Commission and deliver a copy of the recommendation to the tribe. The Office of Self-Regulation's recommendation shall state the reasons for the recommendation and shall advice the tribe of its right to a hearing under part 584 of this chapter or right to appeal under part 585 of this chapter. The Commission may, after an opportunity for a hearing, revoke a certificate of self-regulation by a majority vote of its members if it determines that the tribe no longer meets the eligibility criteria of § 518.3, the approval criteria of § 518.5, the requirements of § 518.10 or the requirements of § 518.11.

§ 518.14 May a tribe request a hearing on the Commission's proposal to revoke its certificate of self-regulation?

Yes. A tribe may request a hearing regarding the Office of Self-Regulation's recommendation that the Commission revoke a certificate of self-regulation. Such a request shall be filed with the Commission pursuant to part 584 of this chapter. Failure to request a hearing within the time provided by part 584 of this chapter shall constitute a waiver of the right to a hearing. At any hearing where the Commission considers revoking a certificate, the Office of Self-Regulation bears the burden of proof to support its recommendation by a preponderance of the evidence. The decision to revoke a certificate is a final agency action and is appealable to Federal District Court pursuant to 25 U.S.C. 2714.

Dated: September 27, 2022.

E. Sequoyah Simermeyer,

Chairman.

Jeannie Hovland,

Vice Chair.

[FR Doc. 2022–21948 Filed 10–17–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Parts 207 and 326

RIN 0710–AB13

Civil Monetary Penalty Inflation Adjustment Rule

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is issuing this final rule to adjust its civil monetary penalties (CMP) under the Rivers and Harbors Appropriation Act of 1922 (RHA), the Clean Water Act (CWA), and the National Fishing Enhancement Act (NFEA) to account for inflation.

DATES: This final rule is effective on October 18, 2022.

FOR FURTHER INFORMATION CONTACT: For the RHA portion, please contact Mr. Paul Clouse at 202–761–4709 or by email at *Paul.D.Clouse@usace.army.mil,* or for the CWA and NFEA portion, please contact Mr. Matt Wilson 202–761–5856 or by email at *Matthew.S.Wilson@usace.army.mil* or access the U.S. Army Corps of Engineers Regulatory Home Page at *https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/.*

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, codified at 28 U.S.C. 2461, note, as amended, requires agencies to annually adjust the level of CMP for inflation to improve their effectiveness and maintain their deterrent effect, as required by the Federal Civil Penalties Adjustment Act Improvements Act of 2015, Public Law 114–74, sec. 701, November 2, 2015 (''Inflation Adjustment Act'').

With this rule, the new statutory maximum penalty levels listed in Table 1 will apply to all statutory civil penalties assessed on or after the effective date of this rule. Table 1 shows the calculation of the 2022 annual inflation adjustment based on the guidance provided by the Office of Management and Budget (OMB) (see December 15, 2021, Memorandum for the Heads of Executive Departments and Agencies, Subject: Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015). The OMB provided to agencies the cost-of-living adjustment multiplier for 2022, based on the Consumer Price Index for All Urban Consumers (CPI–U) for the month of October 2021, not seasonally adjusted, which is 1.06222. Agencies are to adjust ''the maximum civil monetary penalty or the range of minimum and maximum civil monetary penalties, as applicable, for each civil monetary penalty by the cost-of-living adjustment.'' For 2022, agencies multiply each applicable penalty by the multiplier, 1.06222, and round to the nearest dollar. The multiplier should be applied to the most recent penalty amount, *i.e.,* the one that includes the 2021 annual inflation adjustment.

TABLE 1

Citation	Civil Monetary Penalty (CMP) amount established by law	2021 CMP amount in effect prior to this rulemaking	2022 Inflation adjustment multiplier	CMP Amount as of October 18, 2022
Rivers and Harbors Act of 1922 (33 U.S.C. 555).	$2,500 per violation	$5,903 per violation	1.06222	$6,270 per violation.
CWA, 33 U.S.C. 1319(g)(2)(A).	$10,000 per violation, with a maximum of $25,000.	$22,585 per violation, with a maximum of $56,461.	1.06222	$23,990 per violation, with a maximum of $59,974.
CWA, 33 U.S.C. 1344(s)(4) ...	Maximum of $25,000 per day for each violation.	Maximum of $56,461 per day for each violation.	1.06222	Maximum of $59,974 per day for each violation.