DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2017–N–0011]

Civil Money Penalty Definitions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending a civil money penalty regulation to correct a statutory reference to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective July 25, 2017.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION: FDA is amending its regulation at 21 CFR 17.3 to correct a statutory reference to reflect the current citation. FDA is revising § 17.3(a)(1) through (4) by replacing section ''333(g)'' with section ''333(f).'' On July 27, 1995, FDA published a final rule establishing hearing procedures for use when FDA proposes the imposition of administrative civil money penalties (60 FR 38612 at 38626). The document was published with a citation to 21 U.S.C. 333(g) (303(g) of the FD&C Act) that subsequently was changed to 21 U.S.C. 333(f) (303(f) of the FD&C Act) by section 226(b)(1) of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).

Publication of this document constitutes final action on the change under the Administrative Procedure Act (5 U.S.C. 553). This technical amendment is nonsubstantive and merely updates and corrects a statutory reference in the Code of Federal Regulations (CFR) that is no longer current. FDA therefore, for good cause, has determined that notice and public comment are unnecessary under 5 U.S.C. 553(b)(3)(B). Further, this rule places no burden on affected parties for which such parties would need a reasonable time to prepare for the effective date of the rule. Accordingly, FDA, for good cause, has determined this technical amendment to be exempt under 5 U.S.C. 553(d)(3) and that the rule can become effective upon publication.

FDA has determined under 21 CFR 25.30(i) that this final rule 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. In addition, FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–20) is not required.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

■ 2. In § 17.3, paragraph (a) is revised to read as follows:

§ 17.3 Definitions.

* * * * *

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(f)(1):

(1) *Significant departure,* for the purpose of interpreting 21 U.S.C. 333(f)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(i), means a departure from a requirement taken:

(i) With actual knowledge that the action is such a departure; or

(ii) In deliberate ignorance of a requirement; or

(ii) In reckless disregard of a requirement.

(3) *Minor violations,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective,* for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

* * * * *

Dated: July 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15532 Filed 7–24–17; 8:45 am]

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DEPARTMENT OF INTERIOR

National Indian Gaming Commission

25 CFR Part 515

RIN 3141–AA65

Privacy Act Procedures; Corrections

AGENCY: National Indian Gaming Commission, Department of Interior.

ACTION: Correcting amendments.

SUMMARY: On January 24, 2017, the National Indian Gaming Commission (NIGC) revised its Privacy Act regulations. That document included incorrect information regarding the NIGC's address and contained conflicting timelines for resolving appeals. This document corrects the final regulations.

DATES: Effective July 25, 2017 and applicable beginning January 24, 2017.

FOR FURTHER INFORMATION CONTACT: Andrew Mendoza, Staff Attorney, (202) 632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or the Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law October 17, 1988. The Act established the NIGC and set out a comprehensive framework for the regulation of gaming on Indian lands. The purposes of the Act include: Providing a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments; ensuring that the Indian tribe is the primary beneficiary of the gaming operation; and declaring that the establishment of independent federal regulatory authority for gaming on Indian lands, the establishment of federal standards for gaming on Indian lands, and the establishment of a National Indian

Gaming Commission are necessary to meet congressional concerns regarding gaming and to protect such gaming as a means of generating tribal revenue. 25 U.S.C. 2702.

II. Corrections

25 CFR Part 515—Privacy Act Procedures

This document makes several correcting amendments to the Commission's Privacy Act procedures. First, this document amends 25 CFR 515.7(c) to reflect that the correct timeframe for the Privacy Act Appeals Officer to respond to an appeal is 20 working days rather than 30 working days. In 25 CFR 515.7(c) sentence one, the regulation correctly refers to the twenty-working day period established in the Commission's final rule. Then, in sentence two, the regulation incorrectly refers to the same time period as a thirty working-day period. The Commission addressed this change in its preamble to the final rule and explained that this time period was being changed to reflect the twenty working-day time period established within the Freedom of Information Act. The second reference to this time period was overlooked in the previous publication. This document also amends 25 CFR 515.3 to update the Commission's physical address. This document also corrects a grammatical error in 25 CFR 515.7(c). Finally, it amends a cross-reference contained in 25 CFR 515.10.

III. Certain Findings

Under the Administrative Procedure Act, a notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comments are impractical, unnecessary, or contrary to the public interest. Because the revisions here are technical in nature and are not substantive, the NIGC is publishing a technical amendment.

IV. Regulatory Matters

Executive Order 13175

The National Indian Gaming Commission is committed to fulfilling its tribal consultation obligations—whether directed by statute or administrative action such as Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments)—by adhering to the consultation framework described in its Consultation Policy published on July 15, 2013. Due to the ministerial nature of the action being taken here, consultation is not required under the NIGC's Consultation Policy.

Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities as defined by the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Indian tribes are not considered to be small entities for purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule will not result in an annual effect on the economy of $100 million per year or more. This rule will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates 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 determined the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform Act

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

National Environmental Policy Act

The Commission determined this rule does not constitute a major federal action significantly affecting the quality of the human environment and that a detailed statement is not required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The rule does not contain any information collection requirements for which Office of Management and Budget approval under the Paperwork Reduction Act (44 U.S.C. 3501–3520) is required.

List of Subjects in 25 CFR Part 515

Administrative practice and procedure, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the NIGC amends 25 CFR part 515 as follows:

PART 515—PRIVACY ACT PROCEDURES

■ 1. The authority citation for part 515 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 515.3 by revising the third sentence of paragraph (a) to read as follows:

§ 517.3 Request for access to records.

(a) * * * The request may be made in person at 90 K Street NE., Suite 200, Washington, DC 20002 during the hours of 9 a.m. to 12 noon and 2 p.m. to 5 p.m. Monday through Friday, in writing at NIGC Attn: Privacy Act Office, 1849 C Street NW., Mail Stop #1621, Washington, DC 20240, or via electronic mail addressed to *PARequests@nigc.gov.*
* * * * *

■ 3. Amend § 515.7 by revising the second and sixth sentences of paragraph (c) to read as follows:

§ 515.7 Appeals of initial adverse agency determination.

* * * * *

(c) * * * For good cause shown, however, the Privacy Act Appeals Officer may extend the 20 day working period. * * * The response to the appeal shall also advise of the right to institute a civil action in a federal district court for judicial review of the decision.
* * * * *

■ 4. Amend § 515.10 by revising the first sentence to read as follows:

§ 515.10 Fees.

The Commission shall charge fees for duplication of records under the Privacy Act in the same way in which it charges duplication fees under § 517.9 of this chapter. * * *

Dated: July 14, 2017.

Jonodev O. Chaudhuri,

Chairman.

Kathryn Isom-Clause,

Vice Chair.

E. Sequoyah Simermeyer,

Commissioner.

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