DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

[Docket No. FDA–2017–D–6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance for industry and FDA Staff entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' This guidance describes FDA's intention with respect to the enforcement of unique device identification requirements for certain class I and unclassified devices. FDA does not intend to enforce standard date formatting, labeling, and Global Unique Device Identification Database (GUDID) data submission requirements under Agency regulations for these devices before September 24, 2020. In addition, FDA does not intend to enforce direct mark requirements under an Agency regulation for these devices before September 24, 2022. The policy described in this guidance does not apply to implantable, life-supporting, or life-sustaining devices. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on January 16, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6841 for ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For Center for Devices and Radiological Health-regulated devices:* Loretta Chi, Unique Device Identifier Regulatory Policy Support, 301–796–5995, email: *GUDIDSupport@fda.hhs.gov. For Center*

for Biologics Evaluation and Research-regulated devices: Stephen Ripley, Office of Communication, Outreach, and Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, or call 1–800–835–4709 or 240–402–8010.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' In the September 24, 2013, **Federal Register** (78 FR 58786), FDA published a final rule establishing a unique device identification system designed to adequately identify medical devices during their distribution and use (the UDI Rule). Under § 801.20 (21 CFR 801.20) a device is required to bear a unique device identifier (UDI) on its label and packages unless an exception or alternative applies. Special labeling requirements apply to stand-alone software regulated as a device (§ 801.50 (21 CFR 801.50)). Under § 830.300 (21 CFR 830.300) data pertaining to the key characteristics of each device required to bear a UDI must be submitted to the GUDID. Devices that must bear UDIs on their labels and that are intended to be used more than once and reprocessed between uses must be directly marked with a UDI (§ 801.45 (21 CFR 801.45)). In addition, § 801.18 (21 CFR 801.18) requires certain dates on device labels to be in a standard format.

UDI requirements are being phased in over 7 years according to a schedule of compliance dates established in the UDI Rule ranging from September 24, 2014, to September 24, 2020. The compliance dates established for class I and unclassified devices—other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices—are September 24, 2018, for labeling, GUDID submission, and standard date format requirements, and September 24, 2020, for direct mark requirements.

FDA does not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements under §§ 801.18, 801.20, 801.50, and 830.300 for class I and unclassified devices, other than I/LS/LS devices, before September 24, 2020. FDA also does not intend to enforce direct mark requirements under § 801.45 for these devices before September 24, 2022. This policy does not apply to class I devices that FDA has by regulation exempted from the good manufacturing practice requirements because such devices are excepted from UDI requirements (see § 801.30(a)(2) (21 CFR 801.30(a)(2))).

In addition, finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, are excepted from UDI labeling requirements under §§ 801.20 and 801.50, as well as from GUDID data submission requirements for a period of 3 years after the established compliance date or until September 24, 2021. (See §§ 801.30(a)(1) and 830.300(a).) We also do not intend to enforce standard date format requirements under § 801.18 during that same 3-year period for finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled before September 24, 2018.

Pursuant to § 801.30(a)(1), finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, would also be excepted from direct marking requirements until September 24, 2021. However, with the exception of I/LS/LS devices, we do not intend to enforce direct mark requirements before September 24, 2022, for class I and unclassified devices (including those manufactured and labeled prior to September 24, 2018). We believe this policy regarding direct mark compliance dates is appropriate because it is not in the best interest of the public health for labelers of class I and unclassified devices to prioritize remediating devices in inventory to meet direct mark requirements prior to addressing direct marking, and its impact on the safety and effectiveness, for devices manufactured following labelers' full implementation of UDI.

Fully realizing the benefits of the unique device identification system depends on UDI being integrated into data sources throughout our health care system, including in the supply chain, electronic health records, and registries. This requires UDI data to be of a high quality such that all stakeholders in the health care community have sufficient confidence in the accuracy and completeness of that data.

To fully reap the public health benefits and a return on investment of the unique device identification system, the Agency intends to focus its resources on addressing existing implementation challenges and optimizing the quality and utility of UDI data for higher-risk devices before focusing on UDI implementation issues for lower-risk devices. Undertaking this endeavor now will help ensure the transition from development of the unique device identification system to widespread use and sustainability.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2) (21 CFR 10.115(g)(2))). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* A search capability for all Center for Biologics Evaluation and Research guidance documents is available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17029 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910–0720.

Dated: January 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00550 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 575

Annual Adjustment of Civil Monetary Penalty To Reflect Inflation

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: In compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the Act) and Office of Management and Budget (OMB) guidance, the National Indian Gaming Commission (NIGC or Commission) is amending its civil monetary penalty rule to reflect an annual adjustment for inflation in order to improve the penalty's effectiveness and maintain its deterrent effect. The Act provides that the new penalty level must apply to penalties assessed after the effective date of the increase, including when the penalties whose associated violation predate the increase.

DATES: This final rule will have an effective date of January 15, 2018.

FOR FURTHER INFORMATION CONTACT: Contact Armando J. Acosta, Senior Attorney, Office of General Counsel, National Indian Gaming Commission, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74). Beginning in 2017, the Act requires agencies to make annual inflationary adjustments to their civil monetary penalties by January 15th of each year, in accordance with annual OMB guidance.

II. Calculation of Annual Adjustment

On December 15, 2017, OMB issued guidance to agencies to calculate the annual adjustment. *See* M–18–03 Memorandum for the Heads of Executive Departments and Agencies, from Mick Mulvaney, Director, Subject: *Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (December 15, 2017). According to OMB, the cost-of-living adjustment multiplier for 2018, based on the Consumer Price Index (CPI–U) for the month of October 2017, not seasonally adjusted, is 1.02041.

Pursuant to this guidance, the Commission has calculated the annual adjustment level of the civil monetary penalty contained in 25 CFR 575.4 (''The Chairman may assess a civil fine, not to exceed $50,276 per violation, against a tribe, management contractor, or individual operating Indian gaming for each notice of violation . . .''). The 2018 adjusted level of the civil monetary penalty is $51,302 ($50,276 × 1.02041).

III. Regulatory Matters

Regulatory Planning and Review

This final rule is not a significant rule under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy or will not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not involve entitlements, grants, user fees, or loan programs or the rights or obligations of recipients.

(4) This regulatory change does not raise novel legal or policy issues.

Regulatory Flexibility Act

The Commission certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule makes annual adjustments for inflation.

Small Business Regulatory Enforcement Fairness Act

This final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year. The rule will not result in a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This final rule does not impose an unfunded mandate of more than $100 million per year on state, local, or tribal governments or the private sector. The rule also does not have a significant or unique effect on state, local, or tribal governments or the private sector. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings

Under the criteria in Executive Order 12630, this final rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable ''taking.'' Thus, a takings implication assessment is not required.

Federalism

Under the criteria in Executive Order 13132, this final rule has no substantial direct effect 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.

Civil Justice Reform

This final rule complies with the requirements of Executive Order 12988. Specifically, this rule has been reviewed to eliminate errors and ambiguity and written to minimize litigation. It is written in clear language and contains clear legal standards.

Consultation With Indian Tribes

In accordance with the President's memorandum of April 29, 1994, *Government-to-Government Relations with Native American Tribal Governments,* Executive Order 13175 (59 FR 22951, November 6, 2000), the