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Dated: July 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15350 Filed 7–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2870]

Electronic Submission; Data Standards; Support for Geopolitical Entities, Names, and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the adoption of the current version of the Geopolitical Entities, Names, and Codes (GENC) Standard on December 17, 2020. The GENC Standard is the U.S. Government profile of International Organization for Standardization (ISO) 3166 ''Codes for the Representation of Names of Countries and Their Subdivisions.'' It specifies an authoritative set of country codes and names for use by the U.S. Government for information exchange, using ISO 3166 names and code elements wherever possible, with modifications only when necessary to comply with U.S. law and U.S. Government recognition policy. Adopting the GENC Standard will enable FDA to be in conformance with U.S. Government naming and recognition policies. You may submit comments at any time regarding the appropriateness or timing of FDA's adoption of the GENC Standard.

ADDRESSES: You may submit either electronic or written comments 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–2019–N–2870 for ''Electronic Submission; Data Standards; Support for Geopolitical Entities, Names, and Codes.'' 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.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *cderdatastandards@fda.hhs.gov,* or Stephen Ripley, 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: On December 17, 2015, FDA began supporting GENC as the FDA standard for representing countries and their principal subdivisions. ISO is an organization that creates standards documents to provide requirements, specifications, and guidelines that can be followed by regulatory agencies and industry (*https://nsgreg.nga.mil/genc/discovery*). Before adopting GENC as its standard, FDA represented countries using ISO 3166–1 alpha-3 and represented countries' principal subdivisions using ISO 3166–2. Before adopting ISO 3166 as its standard, FDA represented countries using Federal Information Processing Standards (FIPS) 10–4 and represented principal subdivisions of the United States using FIPS 5–2 (*https://nsgreg.nga.mil/doc/view?i=2564*). FIPS are publicly announced standards developed by the U.S. Government for use in computer systems by nonmilitary Government Agencies and industry.

Public Law 80–242 (1947) requires the U.S. Government to use geographic names that have been approved by the U.S. Board on Geographic Names (BGN). ISO 3166 contains a small set of country

and principal subdivision names that vary from those approved by the BGN. The geopolitical entities included in ISO 3166 are those that are recognized by the United Nations. Therefore, GENC is the U.S. Government implementation of ISO 3166 that conforms to BGN and U.S. Government recognition policy and will enable FDA to be in conformance with U.S. Government naming and recognition policies. The GENC Standard is specified by the combination of a stable information design document and information content consisting of dynamically managed entries in the GENC Registry. In accordance with OMB Circular A–119 (*https://obamawhitehouse.archives.gov/omb/circulars_a119_a119fr*), Federal Agencies are directed to use voluntary consensus standards in lieu of government-unique standards except when inconsistent with law or otherwise impractical. ISO 3166 is the base standard for the profile that is the GENC Standard. The GENC Standard asserts both restrictions to, and extensions of, the ISO 3166 base standard; it is a Class 2 profile in accordance with the provisions of ISO 19106 (*https://www.iso.org/standard/26011.html*). Information regarding the development of the GENC Standard can be found at *https://nsgreg.nga.mil/geopoliticalCode.jsp.* Frequently asked questions regarding the content and use of the GENC Standard can be found at *https://nsgreg.nga.mil/genc/faq.jsp?register=0.*

The information content of the GENC Standard is specified with respect to ISO 3166 (Parts 1 and 2). Entries of the GENC Standard are based on either direct reuse of ISO 3166 code elements or a type of variation from that standard (Exclusion, Exception, Extension, or Exigent) based on U.S. government requirements. In the case of Exceptions, the *codes do not differ* from ISO 3166. Exceptions are based on differences in naming (some politically significant, others simply stylistic) as approved by the BGN, or differences in how the territorial extent of an entity is understood. GENC Extensions introduce entities not included in ISO 3166. Entries from ISO 3166 that are *excluded* from the GENC Standard may be browsed in the GENC Registry.

Infrequently, ISO 3166–1 code elements for a given country name are revised for reasons that are not related to a change in the country name itself. Consequently, a given country name may be assigned differing code element values over time. To enable information systems to easily recognize these occasions, a file specifying country code element correspondences is maintained in the NSG-unique Standards Register (*https://nsgreg.nga.mil/doc/view?i=2563*).

For those occasions when it may be necessary to reference the names of countries that are not included in the content of the GENC Standard because of the disestablishment of those countries before the initial publication of the GENC, the Codes for Historical Country Names information guidance document specifies applicable codes and their corresponding names for use in ''country coding'' such data (this information can be found at *https://nsgreg.nga.mil/doc/view?i=2565*).

While FDA currently supports the GENC standard, the FDA Data Standards Catalog will be updated to announce an implementation date of December 17, 2020, for GENC. After receiving comments, the Agency may consider further actions regarding the adoption of the GENC standard and/or its planned implementation date.

Dated: July 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Ryan White HIV/AIDS Program (RWHAP) Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 17, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–xxxx–New.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states and territories, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people diagnosed with HIV. Nearly two-thirds of RWHAP clients live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people diagnosed with HIV (more than 50 percent of all people diagnosed with HIV in the United States).

Grant recipients funded under Parts A, B, C, and D of RWHAP (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of each grant budget period (Expenditures Report) using the HRSA Electronic Handbooks (EHBs).[1] HRSA RWHAP's Parts A and B collect unobligated balances (UOB) of federal funds and rebate addendum information by subprogram from their grant recipients. Parts A and B use the UOB and rebate addendum financial information to determine formula funding as directed by RWHAP statute. These data were collected when grant recipients submitted their annual Federal Financial Report (FFR SF–425) in hard copy only, and submitted to the individual HHS Operating Divisions (OPDIVs). HRSA combined the FFR SF–425 with the UOB and rebate addendum

[1] The Allocations Report and the Expenditures Report were approved by OMB under the 0915–0318 control number.