ATTENTION: FDA Industry Systems Users

Change of International Organization for Standardization (ISO) 3166 Data Standards

Effective January 30, 2021, the FDA Unified Registration and Listing Systems (FURLS) will replace the use of ISO-3166 data standards with the <u>Geopolitical Entities</u>, <u>Names</u>, <u>and Codes Standard (nga.mil)</u> for populating country, state/province/territory codes and names within its systems.

Background:

United States Public Law (80-242) requires the U.S. Government to use geographic names that have been approved by the Board of Geographic Names (BGN). The implementation of GENC Standard ensures that FURLS systems comply with U.S. law and U.S. Government recognition policy and fulfill FDA requirements.

Going forward, industry users will automatically use the GENC Standard for geographic name data entries throughout the FURLS applications. This enhancement complies with and improves the interoperability between FURLS and other FDA systems. Users will receive documents from the FURLS system with naming conventions that are consistent with U.S. Government standards. The adoption of the GENC Standard will better facilitate FURLS industry users in conducting business within the U.S. and overseas.

Impact to FDA Industry Systems Users:

Most users will not be impacted by this change as most of the country, state/province/territory codes and names will remain the same. For the entities that are impacted by the implementation of GENC Standard (see below), updates will be applied automatically throughout FURLS and its downstream systems to reflect the changes. No action is required on the users' part.

Please contact the FURLS Help Desk with any questions regarding the update:

Phone: 1-800-216-7331 or 240-247-8804 (Hours of Operation: 7:30 AM -11:00 PM, EST)

Fax: 301-436-2804 or 1-866-573-0846

Email: FURLS@fda.gov

Listed below are some examples of country names and code changes:

ISO 3166 to GENC Country Name Changes:

ISO Code	ISO NAME	GENC Name	GENC Code
BS	Bahamas	Bahamas, The	BS
МК	Macedonia, The Former Yugoslav Republic Of	Macedonia	MK
PN	Pitcairn	Pitcairn Islands	PN
TF	French Southern Territories	French Southern and Antarctic Lands	TF
SZ	Swaziland	Eswatini	SZ
VA	Holy See (Vatican City State)	Vatican City	VA
VE	Venezuela, Bolivarian Republic of	Venezuela	VE
CD	Congo, The Democratic Republic of The	Congo (Kinshasa)	CD
CG	Congo	Congo (Brazzaville)	CG
CI	Cote D'Ivoire	Côte d'Ivoire	CI

ISO 3166 to GENC Country Code Changes/Merge:

ISO	GENC	Name
WE	XW	West Bank
YD	YE	Yemen
BU	MM	Burma
AN	CW	Curaçao
AX	FI	Finland
GZ	XG	Gaza Strip
KV	XK	Kosovo
AC	SH	Saint Helena, Ascension, and Tristan da Cunha
CS	RS	Serbia
TP	TL	Timor-Leste

Country Codes Added to FURLS:

Code	Name	Code	Name
XJ	Jan Mayen	XH	Howland Island
QU	Juan De Nova Island	QZ	Akrotiri
XU	Johnston Atoll XD Dhekelia		Dhekelia
QM	Midway Islands	A2	Guantanamo Bay Naval Base
XC	Coral Sea Islands	XT	Tromelin Island
A3	Entity 6	XB	Baker Island
XL	Palmyra Atoll	BQ	Bonaire, Sint Eustatius, And Saba
CP	Clipperton Island	XA	Ashmore And Cartier Islands
XQ	Jarvis Island	QS	Bassas Da India
QX	Glorioso Islands	A1	Unknown
XE	Europa Island	XS	Spratly Islands
QW	Wake Island	XV	Navassa Island
XP	Paracel Islands	DG	Diego Garcia

Country Codes Removed from FURLS:

ISO	Name
SJ	Svalbard And Jan Mayen
YU	Yugoslavia
PS	Palestinian Territory, Occupied
UM	United States Minor Outlying Islands