December 19, 2016

Ulrike Kreysa
GS1 Global Office
Blue Tower, Avenue Louise 326, bte 10
B-1050 Brussels, Belgium

Dear Ulrike Kreysa,

Thank you for submitting GS1's application for renewal of accreditation as an issuing agency received on June 17, 2016 ("renewal application"), and the additional information in support of that renewal application received on October 7, 2016.

As we have previously communicated to you, based on our initial experience with the issuing agency framework, FDA has determined that it needs to conduct an evaluation of what an issuing agency's system should include to satisfy the accreditation criteria set forth at 21 CFR 830.100(b). FDA has not yet completed that evaluation process and, consequently, has not yet reached a final decision on your renewal application. Therefore, in accordance with 21 CFR 830.110(c)(5), the approval of GS1's initial application for accreditation is deemed extended until FDA reaches a final decision on the renewal application. Your accreditation remains non-exclusive and subject to the provisions of 21 CFR part 830 and all conditions of approval identified in FDA's accreditation letter to GS1 dated December 17, 2013. FDA may request additional information at a later date in connection with your renewal application, and we are committed to providing an appropriate amount of time for responses to any such future requests. We plan to keep you apprised of the status of the evaluation process.

For additional information, please contact the FDA UDI Help Desk.

Sincerely,
/s/
Linda Sigg
Associate Director of Informatics
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
Food and Drug Administration