DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave.
WO66, Suite 5400
Silver Spring, MD 20993-0002

February 12, 2014

Pat Distler
ICCBBA
PO Box 11309
San Bernardino, CA 92423-1309

Dear Ms. Distler,

The U.S. Food and Drug Administration (FDA) approves your application for accreditation filed on February 12, 2014 and hereby accredits you to act as an "issuing agency" under Subpart C (FDA Accreditation of an Issuing Agency) of Part 830, Title 21, Code of Federal Regulations (CFR), published as part of the Unique Device Identification (UDI) Final Rule, 78 FR 58817, at 58823 (Sep. 24, 2013). The UDI Final Rule implements Sections 510(e) and 519(f) of the Federal Food, Drug and Cosmetic Act, 21 USC 321 et seq., as amended, calling for FDA to establish a uniform system for the identification of medical devices throughout their distribution and use.

This accreditation letter authorizes your organization to issue unique device identifiers (UDIs) to identify the medical devices of labelers participating with you in meeting the requirements of 21 CFR § 830.20 and the compliance dates of the UDI Final Rule. The term of your authorized accreditation is three (3) years, 21 CFR § 830.110(f), and will expire on February 12, 2017 unless the accreditation is renewed, or earlier terminated or relinquished, in accordance with the UDI Final Rule.

The accreditation authorized by this letter is non-exclusive and is subject to the provisions of part 830, including your organization's continued compliance with the eligibility and accreditation criteria set forth in 21 CFR § 830.100. Your responsibilities as an accredited issuing agency are set forth in 21 CFR § 830.120, including to provide us an electronic list of labelers using your system for UDI assignment by December 31 of each year. In accordance with 21 CFR § 830.110(c)(3), as a condition of approval, ICCBBA must notify FDA before making any change in the format or structure of the UDI, and ICCBBA may not implement that change until approved by FDA.

FDA may suspend or revoke the accreditation of an issuing agency if, after providing it with notice and opportunity for an informal hearing in accordance with Part 16, Title 21, CFR, FDA determines that the accredited issuing agency has failed to fulfill its responsibilities or for any other reason set forth in 21 CFR § 830.130. Under 21 CFR § 830.200, FDA reserves its authority to act as an issuing agency if necessary to ensure the continuity or the effectiveness of the UDI

system, if a significant number of small businesses would be substantially and adversely affected by the fees required by accredited issuing agencies, or if appropriate to facilitate or implement an individually granted alternative to the UDI system.

We look forward to working with your organization and participating labelers to assure timely implementation of the UDI system.

Sincerely,

Nancy K. Stade -A

Digitally signed by Nancy K. Stade -A
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Date: 2014.02.12 16:32:23 -05'00'

Nancy K. Stade, J.D.
Deputy Director for Policy
Center for Devices and Radiological Health