20 December 2013

Dear CDRH,

Pursuant to your email of October 18, 2013, we understand the following information must be submitted for our application for an approved UDI issuing agency.

(i) Name, address, and phone number of the applicant;
(ii) Detailed descriptions of any standards or criteria the applicant will apply to participating labelers;
(iii) A detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device;
(iv) A detailed description of the review and decision making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including:
    a. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system;
    b. Policies and procedures for notifying a labeler of deficiencies in its use of UDIs;
    c. Procedures for monitoring a labeler's correction of deficiencies in its use of UDIs;
    d. Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process.
(v) Description of the applicant's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;
(vi) Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available;
(vii) Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies); and
(viii) How the organization protects against conflicts of interest that may impede the issuing agency's ability to independently operate a fair and neutral identifier system;

In addition, though it does not need to accompany the application at this time, we request that you provide a list of labelers that use your system for the assignment of UDIs.

Please submit this information by DIRECT REPLY to this email. The FDA UDI Help Desk will review your request and contact you if any additional information is necessary.

We have provided this information on the attached pages. All documents referred to in the response to your questions can be found in attachments to the PDF. Please let us know if you need any additional information.

Finally, we would like FDA to know that ICCBBA has entered into Memoranda of Understanding with both GS1 and GMDN so that we can work cooperatively with these organizations to better serve the needs of the medical device industry.

Sincerely,

Pat Distler

Technical Director

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(iv) A detailed description of the review and decision making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including: 8

- a. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system 8
- b. Policies and procedures for notifying a labeler of deficiencies in its use of UDIs 8
- c. Procedures for monitoring a labeler's correction of deficiencies in its use of UDIs 9
- d. Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process 9

(v) Description of the applicant's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems 10

(vi) Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available 11

(vii) Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies) 12

(viii) How the organization protects against conflicts of interest that may impede the issuing agency's ability to independently operate a fair and neutral identifier system 13

(ix) In addition, though it does not need to accompany the application at this time, we request that you provide a list of labelers that use your system for the assignment of UDIs. 14

(i) Name, address, and phone number of the applicant

Pat Distler
ICCBBA
PO Box 11309
San Bernardino, CA 92423-1309
1-909-793-6516

Street Address (**after January 6, 2014**):
1901 Orange Tree Lane, Suite 200
Redlands, CA 92374

Street address (**prior to January 6, 2014**)
1200 Orange Tree Lane, Suite 106
Redlands, CA 92374

(ii) Detailed descriptions of any standards or criteria the applicant will apply to participating labelers

Labelers will be required to follow the ISBT 128 Standard Technical Specification (tracking number ST-001) the primary standards document for ISBT 128. It describes the data structures and the bar code symbologies that may be used.

Code 128 must be used for linear bar codes and Data Matrix must be used for 2D bar codes. Users must follow the appropriate ISO standards for the printing of these data structures:

- ISO/IEC 15415:2011(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Two-dimensional symbols (and correction ISO/IEC 15415:2004/Cor 1:2008).
- ISO/IEC 15416:2000(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols
- ISO/IEC 15417: 2007(E): Information technology—Automatic Identification and data capture techniques—Code 128 bar code symbology specification
- ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix (and correction ISO/IEC 16022:2006/Cor 1:2008**)**

Some additional rules (e.g., white space and minimum X value) are defined in the ISBT 128 Standard Technical Specification.

HCT/P Facilities: The document Coding and Labeling of Medical Devices Using ISBT I28 (ST-011) also provides requirements for the use of ISBT 128 that are specific to medical devices.

Certain data structures are required for HCT/Ps labeled with ISBT 128. These are:

Device Identifier: Data Structure 034 (Processor Product Identification Code)

This data structure includes three elements:

- Facility Identification Code (assigned by ICCBBA to uniquely identifier the labeler)
- Facility Product Code
- Standardized Product Description Code

The Facility Identification Code and a Standardized Product Description Code must be assigned. The Facility Product Code may be the default of 000000.

Required production identifiers:

- Data Structure 001 (Donation Identification Number)

- Data Structure 032 (Product Divisions) used as the serial number

Other production identifiers (expiration date, manufacturing date, and lot number), if they appear on the label, must also be included in the UDI bar code.

Because a standardized product description code must be used, labelers must also be familiar with tissue or cellular therapy product description code terminology. This is found in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.

Blood Bag Vendors: Vendors of blood containers must follow the requirements in Sections 2.4.17, 2.4.18, and 7.4 of the ISBT 128 Standard Technical Specification.

(iii) A detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device

A number of guidance documents exist to help users implement ISBT 128 for medical devices. They include:

- Coding and Labeling of Medical Devices Using ISBT I28 (ST-011) (This document contains both requirements and guidance)
- Use of Data Matrix Symbols with ISBT 128 (IG-014)
- Use of Product Divisions [Data Structure 032] (IG-023)
- Use of Donation Identification Number [Data Structure 001] (IG-033)
- ISBT 128 Facility Identification Number (IG-034)

ICCBBA operates a help desk available by telephone (909.793.6516) or email (iccbba@iccbba.org) to assist users. The ICCBBA website (www.iccbba.org) also provides guidance

(iv) A detailed description of the review and decision making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including:

The use of ISBT 128 is open to facilities that manufacture HCT/Ps. US facilities must be registered with FDA for HCT/Ps as listed in the FDA database (https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm).

Applicants must complete a registration form and submit annual updates.

Once an application is received, ICCBBA verifies it is from a registered cell or tissue establishment using the FDA website.

a. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system

Please find attached:

FM-025 Facility Registration Form (for HCT/P facilities)

Facilities License Agreement (for HCT/P facilities)

When HCT/P facilities register with ICCBBA, they are sent an email outlining where information about ISBT 128 may be found on the ICCBBA website. Please see Collection Facility Letter and Email to New Facilities.

Facilities are also asked to update ICCBBA on an annual basis of their activities. Please see FM-058 Facility Annual Return (for HCT/P facilities)

FM-026 Application for Vendor Registration (for manufacturers of blood bags)

FM-074 Vendor Information

Vendor License Agreement

Vendor Welcoming Letter

b. Policies and procedures for notifying a labeler of deficiencies in its use of UDIs

Please see PP-058 Medical Devices – Notification of Nonconformities in the Use of ISBT 128

FM-076 Deficiency Investigation

FM-077 Notification of Nonconformities in the Use of ISBT 128

c. Procedures for monitoring a labeler's correction of deficiencies in its use of UDIs

Please see PP-059 Medical Devices - Monitoring Facility Compliance with Corrective Action Plan

FM-078 Corrective Action Progress Record

d. Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process

Please see PP-060 Medical Devices – Suspending or Revoking License to Use ISBT 128

(v) Description of the applicant's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems

ICCBBA plans to maintain a database of registered facilities using ISBT 128 for UDI. This database will include the name, facility identification number, address, country, national identification number (in the US, FDA registration number), date of registration, current status (active, suspended, revoked, or inactive), contact person, telephone number, email address, website. An output of the US facilities in this file could be provided to FDA in a CSV file. Because we are limited to providing a system for manufacturers of HCT/Ps, we do not anticipate a large volume of data will be submitted.

(vi) Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available

HCT/P Medical Device Facilities

Registration Fee: One-time payment of US$200 which includes allocation of the first Facility Identification Number (FIN). Additional FINs can be requested at US$150 each.

Annual License Fee: This fee is based on the number of HCT/P medical devices produced in the previous year.

If	Then
The facility labels ≤ 1,000 HCT/P medical devices a year	The annual license fee is US$213
The facility labels between 1,000 and 5,000 HCT/P medical devices a year	The annual license fee is US$325
The facility labels >5,000 HCT/P medical devices a year	The annual license fee will be US$325 plus US$0.11 times the number of labeled products per year above 5,000. For example, the facility labels 8,000 products per year. Fee is US$325 + (3,000 * 0.11) = US$655 per year.

(vii) Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies)

There is no financial relationship between ICCBBA and any potential applicant or government entity.

Staff from a labeler could be invited to become a voting member of a TAG or appointed to the ICCBBA Board of Directors. Users may also become observers on a TAG. Observers have opportunity to participate in discussions, but do not vote.

FDA staff may also serve as liaisons on TAGs.

(viii) How the organization protects against conflicts of interest that may impede the issuing agency's ability to independently operate a fair and neutral identifier system

ICCBBA is a small non-profit organization based in Redlands, California, with an approximately 10-member volunteer board of directors.

- There is transparency in how the ISBT 128 standard is managed: Suggested changes to the standard are submitted by any user using a standard proposal form. The proposals are shared with all users via the ICCBBA website and circulated via email to all Technical Advisory Group (TAG) participants. Each proposal is reviewed and voted upon by affected TAGs. Once approved by the TAGs, the ICCBBA standards committee (comprised of the chairmen of the TAGs and additional experts on the ISBT 128 standard) must approve the change.

  Approved changes are then included into the appropriate draft document. Draft documents are published for public comment and are reviewed by the appropriate TAG(s) as well as the Standards Committee. Once changes are approved, the documents are published and the changes are implemented.

- TAG membership varies by product category (blood, cellular therapy, tissues, or human milk). For cellular therapy, global professional societies appoint members and ICCBBA selects hands-on experts to serve. For tissues, the American Association of Tissue Banks co-sponsors the North American Tissue Technical Advisory Group and selects representatives from within its membership. Governmental agencies and other standards setting organizations such as GS1 are invited to appoint liaisons to any ICCBBA TAG.

- A volunteer Board of Directors reviews ICCBBA policies, including fees for use of the standard. Board members are selected via a transparent process: Openings are advertised in professional newsletters and on professional society websites, nominations are collected and reviewed by a subcommittee of Board members. Members are selected to ensure geographical and expertise balance.

- The Board members and the executive director sign a conflict of interest declaration before serving. (Please see FM-080 Declaration of Interests for ICCBBA Board Members and FM-079 Declaration of Interests for ICCBBA Executive Director)

- All ICCBBA meetings and conference calls are preceded with a call for declaration of conflict of interest. (Please see NATTAG Agenda 1 Oct 2013 for an example.)

(ix) In addition, though it does not need to accompany the application at this time, we request that you provide a list of labelers that use your system for the assignment of UDIs.

This information will be provided at a later date.

Name of Issuing Agency: ICCBBA
Date Application Received: December 20, 2013; Supplemental information January 16, 2014
How was the request received by the FDA? Email sent from Pat Distler

1. Is the issuing agency a private organization? Yes, see supplemental information
2. Does the agency's system employ UDIs that meet the requirements of 21 CFR 830.20 to adequately identify a device through its distribution and use? Yes, see supplemental information
3. Will the issuing agency make available information concerning its system for the assignment of UDIs? Yes, page 7 of the Original Application states "ICCBBA operates a help desk available by telephone (909.793.6516) or email (iccbba@iccbba.org) to assist users. The ICCBBA website (www.iccbba.org) also provides guidance."
4. Will the issuing agency maintain a list of labelers that use its system for the assignment of UDIs and be able to and provide FDA a copy of such list in electronic form by December 31 of each year? States page 14 of original application that 'this information will be provided at a later date.' We will have to include in approval letter when we want this first list and that they need to provide by 12/31 of every year.
5. Does the agency's system conform to the following international standards? Yes, see supplemental information
    a. ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition, March 1, 2006);
    b. ISO/IEC 1549-4:2008, Information technology—Unique identifiers—Part 4: Individual items (second edition, July 7, 2008);
    c. ISO/IEC 1549-6:2007, Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition, June 15, 2007).
6. Does the agency's system only use characters and numbers from the invariant character set of ISO/IEC 646? Yes, see supplemental information
7. Is the agency's system available to all users according to a single set of consistent, fair, and reasonable terms and conditions? States on page 8 of original application "The use of ISBT 128 is open to facilities that manufacture HCT/Ps." The system, however, appears to operate according to a single set of consistent, fair, and reasonable terms and conditions.
8. Will the agency protect against conflicts of interest between the issuing agency (and its officers, employees, and other agents) and labelers (and their officers, employees, and other agents) seeking to use UDIs that may impede the applicant's ability to independently operate a fair and neutral identifier system? Yes, Section viii, page 13 describes how ISBT 128 standard is managed, TAG membership, ICCBBA policies, and conflicts of interests (Attachment 23-25). Additionally, on page 2, states that ICCBA has entered into MoUs with GS1 and GMDN.
9. Did the applicant provide the FDA with an application containing the following information?
    a. Name, address, and phone number of the applicant; Page 4, Section i:
    Pat Distler, Pat.distler@iccbba.org
    Mailing Address: Pat Distler
    ICCBBA
    PO Box 11309

San Bernardino, CA 92423
909-793-6516

b. Detailed description of any standards or criteria the applicant will apply to the participating labelers; Section ii, pg 5 of Original Application; Attachment 01: ISBT 128 Standard Technical Specification includes standards
c. Detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device Section iii, pg 7 of Original Application. Attachment 02, Coding and Labeling of Medical Devices Using ISBT I28 (ST-011), contains information on the DI and PIs.
d. Detailed description of the review and decision-making process the applicant will apply when determining whether a particular labeler may use the applicant's UDI system, including: Yes, section iv, pg 8-9 of Original Application. On page 8 of original application, states "Once an application is received, ICCBBA verifies it is from a registered cell or tissue establishment using the FDA website."
    i. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to medical device labelers who wish to use the applicant's unique device identification system; Referenced Section iv.a, pg 8 of Original Application- included copies in attachments. Attachment 08: Facility Registration Form; 09: Facilities License Agreement; 10: Collection Facility Letter; 11: Email to New Facilities; 12: Facility Annual Return; 13: Application for Vendor Registration; 14: Vendor Information; 15: Vendor License Agreement; 16: Vendor Welcoming Letter
    ii. Policies and procedures for notifying a labeler of deficiencies in its use of UDIs; Referenced Section iv.b, pg 8 of Original Application and included attachments 17-19. Attachment 17 describes the method of being notified and how ICCBBA reacts, including creating a corrective action plan. Attachment 18 is the Deficiency Investigation form, and attachment 19 is the Notification of Nonconformities that gets emailed to the deficient body.
    iii. Procedures for monitoring a labeler's correction of deficiencies in its use of UDIs Referenced Section iv.c, pg 9 of Original Application and included attachments 20-21. Attachment 20 outlines the process to monitor the progress of facilities in correcting deficiencies in the implementation or use of ISBT 128 and attachment 21 is the Corrective Action Progress Record.
    iv. Policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process. Referenced Section iv.d, pg 9 of Original Application and included attachment 22 that defines the process to suspend or revoke the license to use ISBT 128
e. Description of the applicant's electronic data management system with respect to its review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems; Mentioned section v., pg 10 of Original Application will provide FDA with CSV files
f. Fee schedules, if any, together with an explanation of any fee waivers or reductions that are available; Fee Schedule pg. 11 of Original Application;

Registration fee ($200 for first FIN; $150 each additional FIN) and annual license fee [$213, $325, or (325+(0.11*(n-5000))) where n=number of labeled products per year] depending on the number of HCT/P medical devices produced in the previous year. See supplemental information about fee waivers and reductions

g. Detailed information regarding any financial or other relationship between the applicant and any labeler(s) or governmental entity(ies); Yes, section vii, page 12 of Original Application.
h. Other information required by FDA to clarify the application for accreditation. See below

If the application is found deficient, date and description of Request for Corrections: The following additional information was requested on January 13, 2014:

1. Explicitly state whether or not ICCBBA is a private organization. Yes
2. State whether ICCBBA's UDIs conform to each of the following international standards: ISO/IEC 15459-2:2006(E); ISO/IEC 1549-4:2008; ISO/IEC 1549-6:2007. Please also provide us with ICCBBA's Issuing Agency Code. Yes
3. State whether ICCBBA uses only characters and numbers from the invariant character set of ISO/IEC 646. Yes
4. State whether any fee waivers or reduction are available. If fee waivers or reductions are available, please describe. Fees are reduced in countries classified as low or medium Human Development Index. Fees are waived for government regulators, governmental and other organizations with an interest in vigilance and surveillance, and professional societies involved in accreditation
5. With the addition of MPHO Supplemental Identification Number and MPHO Supplemental Lot Number, please describe any changes to the UDI.
   a. Could a UDI have both a DIN and MPHO Supplemental Lot Number? Previously, for HCT/Ps, the Lot/Batch Number flag was to be checked in GUDID if the UDI contained a DIN, but with the addition of the MPHO Supplemental Lot Number an additional checkbox may be needed in GUDID. In supplemental information, yes, UDI could have both DIN and a Lot Number- agree additional checkbox needed in GUDID for DIN
   a. Please explain the statement "If an additional identification number (e.g., supplemental serial number) exists, it may be encoded as part of the ISBT 128 data (not a PI) using Data Structure 036, MPHO Supplemental Identification Number." Would the MPHO Supplemental Identification Number never be a PI in the UDI, but could be included in the UDI? In supplemental info, "There cannot be two serial numbers in the UDI…it cannot be part of the PI". Additional information may be encoded in the bar code, but will not be part of the easily readable plain-text UDI. See help desk case 0114-00016606.
   b. What will be the maximum length of an ICCBBA issued UDI? In supplemental information, 79 human readable characters, 67 database characters.

Application Decision:
Date Decision Communicated to Issuing Agency: [insert date accreditation letter signed]
Date by Which Agency Must Renew Its Accreditation: [insert date 3 years from date signed]

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- Close Window
- Print This Page
- Expand All | Collapse All

Case: 0114-00016606

Case Owner	Erin Fields	**Case Record Type**	UDI
Case Number	0114-00016606	**Status**	Closed
Case Origin	Web	**Type**	Regulatory/Policy
		Sub-Type	
		Priority	

Contact Information

Contact Name	Patricia Distler	**Contact Phone**	(909) 793-6516
Organization Name	ICCBBA	**Contact Email**	pat.distler@iccbba.org

Description Information

Subject information in "PI bar code"

Description May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?

Web Information

First Name	Pat	**Web Company**	ICCBBA
Last Name	Distler	**Web Email**	pat.distler@iccbba.org
		Web Phone	(909) 793-6516

System Information

Created By	Salesforce Administrator, 1/14/2014 11:28 AM	**Last Modified By**	Erin Fields, 1/30/2014 8:41 AM

Contact Information

Contact Owner	Indira Konduri	**Phone**	(909) 793-6516
Name	Ms. Patricia Distler	**Mobile**	
Organization Name	ICCBBA	**Email**	pat.distler@iccbba.org
Title		**Reports To**	
Contact Source	UDI Helpdesk		

Address Information

Primary Address	**Secondary Address**

Additional Information

Fax		Department	
Home Phone		Assistant	
Other Phone		Asst. Phone	
Description			

System Information

Created By	Indira Konduri, 10/1/2013 8:25 AM	Last Modified By	Indira Konduri, 10/1/2013 8:25 AM

Custom Links

Google Search Google Maps Send Gmail

Case Comments

1/30/2014 8:41 AM

User	**Erin Fields**
Public	☐
Comment	**responses ended 1/30/14**

Emails

FDA UDI Help Desk Case 0114-00016606

Message Date	**1/30/2014 8:40 AM**
Has Attachment	☐
Email Address	**pat.distler@iccbba.org**
Status	**Sent**
Subject	**FDA UDI Help Desk Case 0114-00016606**
Text Body	**Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team. Thank you for confirming this information.** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

RE: FDA UDI Help Desk Case 0114-00016606

Message Date	**1/29/2014 5:42 PM**
Has Attachment	
Email Address	**pat.distler@iccbba.org**
Status	**Replied**
Subject	**RE: FDA UDI Help Desk Case 0114-00016606**

Text Body

Dear FDA Help Desk Staff,

My responses to your question are below in red font.

Please let me know if there is additional information I can provide.

Thank you for your help!

Pat

-----Original Message-----
From: noreply@salesforce.com [mailto:noreply@salesforce.com] On Behalf Of GUDID Support
Sent: Wednesday, January 29, 2014 2:17 PM
To: pat.distler@iccbba.org
Subject: FDA UDI Help Desk Case 0114-00016606

Dear Patricia Distler,

Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.

Please confirm: ICCBBA would like to have additional information, such as size, be encoded in the UDI bar code, but this additional information would not be in the easily readable plain-text of the UDI.

Yes, this is correct. Such information would be elsewhere on the label.

Please see 21 CFR 801.40(a). The UDI must be presented in easily readable plain-text and AIDC. The other information in the UDI bar code would only be eye-readable on the device label, separate from the human readable UDI associated with the UDI bar code?

Yes, this is correct.

The Unique Device Identification System does not prohibit the use of additional bar codes on the device label.

Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm> http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

Sincerely yours,

FDA UDI Help Desk Team

==========

Patricia Distler

information in "PI bar code"

May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?

ref:_00Dd0fegA._500j0wCkL:ref

FDA UDI Help Desk Case 0114-00016606

Message Date	**1/29/2014 5:16 PM**
Has Attachment	
Email Address	**pat.distler@iccbba.org**
Status	**Sent**
Subject	**FDA UDI Help Desk Case 0114-00016606**
Text Body	**Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **Please confirm: ICCBBA would like to have additional information, such as size, be encoded in the UDI bar code, but this additional information would not be in the easily readable plain-text of the UDI. Please see 21 CFR 801.40(a). The UDI must be presented in easily readable plain-text and AIDC. The other information in the UDI bar code would only be eye-readable on the device label, separate from the human readable UDI associated with the UDI bar code?** **The Unique Device Identification System does not prohibit the use of additional bar codes on the device label.** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.**

Sincerely yours,
FDA UDI Help Desk Team

==========

Patricia Distler
information in "PI bar code"
May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?

ref:_00Dd0fegA._500j0wCkL:ref

RE: FDA UDI Help Desk Case 0114-00016606

Message Date	**1/29/2014 4:52 PM**
Has Attachment	☑
Email Address	**pat.distler@iccbba.org**
Status	**Replied**
Subject	**RE: FDA UDI Help Desk Case 0114-00016606**

Dear UDI Help Desk Team,

It would be our intent that the UDI eye readable information be shown in a separate area (as on the label example below) from other eye readable information. The human readable would remain as the 79 characters.

The other information in the 2D bar code would be characteristics of the device, not PIs.

We are trying to accommodate a tissue bank's desire to have additional information bar coded, and at the same time, avoid having two bar codes on the label. We accept this may not be possible within the regulatory framework. We do not want this issue to delay our becoming an accredited issuing agency and would appreciate any guidance you could provide in meeting the regulatory requirements.

Pat

Pat Distler

Technical Director

ICCBBA

Phone: 1.909.793.6516

pat.distler@iccbba.org

Text Body

-----Original Message-----
From: noreply@salesforce.com [mailto:noreply@salesforce.com] On Behalf Of GUDID Support
Sent: Wednesday, January 29, 2014 9:19 AM
To: pat.distler@iccbba.org
Subject: FDA UDI Help Desk Case 0114-00016606

Dear Patricia Distler,

Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.

Would the additional information be printed within the eye-readable text of the UDI or with the additional information only be encoded in the bar code? We see that the human readable bar code field size is currently 79 characters and want to know if this length is anticipated to increase.

Additionally, would the additional information be production identifiers? Or are they more like characteristics of the device?

Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm> http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

Sincerely yours,

FDA UDI Help Desk Team

==========

Patricia Distler

information in "PI bar code"

May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?

ref:_00Dd0fegA._500j0wCkL:ref

FDA UDI Help Desk Case 0114-00016606

Message Date	**1/29/2014 12:19 PM**
Has Attachment	☐
Email Address	**pat.distler@iccbba.org**
Status	**Sent**
Subject	**FDA UDI Help Desk Case 0114-00016606**
Text Body	**Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **Would the additional information be printed within the eye-readable text of the UDI or with the additional information only be encoded in the bar code? We see that the human readable bar code field size is currently 79 characters and want to know if this length is anticipated to increase.** **Additionally, would the additional information be production identifiers? Or are they more like characteristics of the device?** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

RE: FDA UDI Help Desk Case 0114-00016606

Message Date	**1/23/2014 9:37 AM**
Has Attachment	☑
Email Address	**pat.distler@iccbba.org**
Status	**Replied**
Subject	**RE: FDA UDI Help Desk Case 0114-00016606**

Dear FDA Help Desk Staff,

I thought that, in addition to my explanation below, an illustration of a possible label might be helpful. In the example below, the bar code includes this information:
=+05000=A9997XYZ100T0944=,000012=A999912345600=>160031&$02010002000500010003000500

This piece of the information &$02010002000500010003000500 indicates the product is 5 cm x 5 cm. The text, however, makes it clear that it is not a part of the UDI.

Pat

From: Pat Distler [mailto:pat.distler@iccbba.org]
Sent: Wednesday, January 22, 2014 10:16 AM
To: 'GUDID Support'
Subject: RE: FDA UDI Help Desk Case 0114-00016606

Dear FDA Help Desk Team:

ISBT 128 has multiple other data structures such as Dimensions, Infectious Markers, internal Identifiers, etc., that tissue banks may want to encode. The dimensions data structure allows facilities to describe the exact size of a tissue (e.g., length and width of a demineralized bone strip); Infectious Markers allows facilities to provide test results on a donor; the Supplementary Identification Number allows an internal tracking number.

This additional encoded information is not intended to be used for unique identification of the product between organizations for purposes of traceability.

Our rules will support that the UDI is used for all traceability purposes.

Pat Distler

Technical Director
ICCBBA

Text Body

-----Original Message-----
From: noreply@salesforce.com <mailto:noreply@salesforce.com> [mailto:noreply@salesforce.com] On Behalf Of GUDID Support
Sent: Friday, January 17, 2014 9:15 AM
To: pat.distler@iccbba.org <mailto:pat.distler@iccbba.org>
Subject: FDA UDI Help Desk Case 0114-00016606

Dear Patricia Distler,

Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.

The content of the human readable UDI should be restricted to only the DI and PIs that have been approved by FDA. The application submitted by an issuing agency for FDA accreditation must contain all information regarding the content of the human readable UDI and the UDI contained in the AIDC, including the data delimiters for the DI and all PIs that are included in the UDI.

Please describe the information that is not part of a UDI that you would like to encode in the AIDC. How would this additional information be used?

Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm> http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

Sincerely yours,

FDA UDI Help Desk Team

==========

Patricia Distler

information in "PI bar code"

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ref:_00Dd0fegA._500j0wCkL:ref

RE: FDA UDI Help Desk Case 0114-00016606

Message Date	**1/22/2014 1:15 PM**
Has Attachment	
Email Address	**pat.distler@iccbba.org**
Status	**Read**
Subject	**RE: FDA UDI Help Desk Case 0114-00016606**

Dear FDA Help Desk Team:

ISBT 128 has multiple other data structures such as Dimensions, Infectious Markers, internal Identifiers, etc., that tissue banks may want to encode. The dimensions data structure allows facilities to describe the exact size of a tissue (e.g., length and width of a demineralized bone strip); Infectious Markers allows facilities to provide test results on a donor; the Supplementary Identification Number allows an internal tracking number.

This additional encoded information is not intended to be used for unique identification of the product between organizations for purposes of traceability.

Our rules will support that the UDI is used for all traceability purposes.

Pat Distler

Technical Director
ICCBBA

-----Original Message-----
From: noreply@salesforce.com [mailto:noreply@salesforce.com] On Behalf Of GUDID Support
Sent: Friday, January 17, 2014 9:15 AM
To: pat.distler@iccbba.org
Subject: FDA UDI Help Desk Case 0114-00016606

Dear Patricia Distler,

Text Body

Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.

The content of the human readable UDI should be restricted to only the DI and PIs that have been approved by FDA. The application submitted by an issuing agency for FDA accreditation must contain all information regarding the content of the human readable UDI and the UDI contained in the AIDC, including the data delimiters for the DI and all PIs that are included in the UDI.

Please describe the information that is not part of a UDI that you would like to encode in the AIDC. How would this additional information be used?

Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm> http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

Sincerely yours,

FDA UDI Help Desk Team

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Patricia Distler

information in "PI bar code"

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ref:_00Dd0fegA._500j0wCkL:ref

FDA UDI Help Desk Case 0114-00016606

Message Date	**1/17/2014 12:15 PM**
Has Attachment	
Email Address	**pat.distler@iccbba.org**

Status	**Sent**
Subject	**FDA UDI Help Desk Case 0114-00016606**
Text Body	**Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **The content of the human readable UDI should be restricted to only the DI and PIs that have been approved by FDA. The application submitted by an issuing agency for FDA accreditation must contain all information regarding the content of the human readable UDI and the UDI contained in the AIDC, including the data delimiters for the DI and all PIs that are included in the UDI.** **Please describe the information that is not part of a UDI that you would like to encode in the AIDC. How would this additional information be used?** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

FDA UDI Help Desk Case# 0114-00016606

Message Date	**1/14/2014 11:28 AM**
Has Attachment	☐
Email Address	**pat.distler@iccbba.org**
Status	**Replied**
Subject	**FDA UDI Help Desk Case# 0114-00016606**
Text Body	**Dear Pat Distler,** **Thank you for contacting the FDA UDI Help Desk.** **A FDA UDI Help Desk Analyst will respond to you as soon as possible.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Pat Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

Activity History

Email: FDA UDI Help Desk Case 0114-00016606

Name	**Patricia Distler**
Task	☑
Due Date	**1/30/2014**
Assigned To	**Erin Fields**
Last Modified Date/Time	**1/30/2014 8:40 AM**
Comments	**Additional To: pat.distler@iccbba.org** **CC:** **BCC: erin.fields@fda.hhs.gov** **Attachment:** **Subject: FDA UDI Help Desk Case 0114-00016606** **Body:** **Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team. Thank you for confirming this information.** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

Email: FDA UDI Help Desk Case 0114-00016606

Name	**Patricia Distler**
Task	☑
Due Date	**1/29/2014**
Assigned To	**Erin Fields**
Last Modified Date/Time	**1/29/2014 5:16 PM**
	Additional To: pat.distler@iccbba.org **CC:** **BCC: erin.fields@fda.hhs.gov** **Attachment:** **Subject: FDA UDI Help Desk Case 0114-00016606** **Body:** **Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **Please confirm: ICCBBA would like to have additional information, such as size, be encoded in the UDI bar code, but this additional information would not be in the easily readable plain-text of the UDI. Please see 21**

	CFR 801.40(a). The UDI must be presented in easily readable plain-text and AIDC. The other information in the UDI bar code would only be eye-readable on the device label, separate from the human readable UDI associated with the UDI bar code?
Comments	**The Unique Device Identification System does not prohibit the use of additional bar codes on the device label.** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

Email: FDA UDI Help Desk Case 0114-00016606

Name	**Patricia Distler**
Task	✔
Due Date	**1/29/2014**
Assigned To	**Erin Fields**
Last Modified Date/Time	**1/29/2014 12:19 PM**
Comments	**Additional To: pat.distler@iccbba.org** **CC:** **BCC: erin.fields@fda.hhs.gov** **Attachment:** **Subject: FDA UDI Help Desk Case 0114-00016606** **Body:** **Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **Would the additional information be printed within the eye-readable text of the UDI or with the additional information only be encoded in the bar code? We see that the human readable bar code field size is currently 79 characters and want to know if this length is anticipated to increase.** **Additionally, would the additional information be production identifiers? Or are they more like characteristics of the device?** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========**

Patricia Distler
information in "PI bar code"
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Email: FDA UDI Help Desk Case 0114-00016606

Name	**Patricia Distler**
Task	☑
Due Date	**1/17/2014**
Assigned To	**Erin Fields**
Last Modified Date/Time	**1/17/2014 12:15 PM**
Comments	**Additional To: pat.distler@iccbba.org** **CC:** **BCC: erin.fields@fda.hhs.gov** **Attachment:** **Subject: FDA UDI Help Desk Case 0114-00016606** **Body:** **Dear Patricia Distler,** **Thank you for your interest in UDI. Your FDA UDI Help Desk case# 0114-00016606 has been reviewed by the FDA UDI Help Desk Team.** **The content of the human readable UDI should be restricted to only the DI and PIs that have been approved by FDA. The application submitted by an issuing agency for FDA accreditation must contain all information regarding the content of the human readable UDI and the UDI contained in the AIDC, including the data delimiters for the DI and all PIs that are included in the UDI.** **Please describe the information that is not part of a UDI that you would like to encode in the AIDC. How would this additional information be used?** **Thank you for your submission. If you have further questions regarding this response, please DIRECTLY REPLY to this email. If you have other questions, please contact the FDA UDI Help Desk here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Patricia Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

Email: FDA UDI Help Desk Case# 0114-00016606

Name	**Patricia Distler**
Task	☑
Due Date	**1/14/2014**

Assigned To	**Salesforce Administrator**
Last Modified Date/Time	**1/14/2014 11:28 AM**
Comments	**Additional To: pat.distler@iccbba.org** **CC:** **BCC:** **Attachment:** **Subject: FDA UDI Help Desk Case# 0114-00016606** **Body:** **Dear Pat Distler,** **Thank you for contacting the FDA UDI Help Desk.** **A FDA UDI Help Desk Analyst will respond to you as soon as possible.** **Sincerely yours,** **FDA UDI Help Desk Team** **==========** **Pat Distler** **information in "PI bar code"** **May information that is not part of a PI (e.g., additional identifiers) be in the same bar code as PI information? That is, can the bar code that carries the PI elements (expiration date and DIN, for example) also have information about the size of the item, additional identifiers, etc.?** **ref:_00Dd0fegA._500j0wCkL:ref**

Case History

1/30/2014 8:41 AM

User	**Erin Fields**
Action	**Changed Status from In-Progress to Closed. Closed.**

1/22/2014 11:57 AM

User	**Erin Fields**
Action	**Changed Type from Technical to Regulatory/Policy.**

1/14/2014 12:53 PM

User	**Anie Mathews**
Action	**Changed Assigned Date from 1/14/2014 12:51 PM to 1/14/2014 12:53 PM. Changed Case Owner from Indira Konduri to Erin Fields.**

1/14/2014 12:51 PM

User	**Anie Mathews**
Action	**Changed Status from New to In-Progress. Changed Assigned By to amath. Changed Assigned Date to 1/14/2014 12:51 PM. Changed Case Owner from UDI Technical to Indira Konduri.**

1/14/2014 11:28 AM

User	**Salesforce Administrator**
Action	**Changed Owner (Assignment) from Salesforce Administrator to UDI Technical. Changed Case Origin to Web. Changed Status to New. Created.**

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1. Explicitly state whether or not ICCBBA is a private organization.

   ICCBBA is a non-stock corporation organized and operated exclusively for charitable, scientific and educational purposes within the meaning of the Section 501(c)(3) of the Internal Revenue Code of 1986, as amended. We believe this meets the definition of a 'private organization' as specified in the final rule.

2. State whether ICCBBA's UDIs conform to each of the following international standards: ISO/IEC 15459-2:2006(E); ISO/IEC 1549-4:2008; ISO/IEC 1549-6:2007. Please also provide us with ICCBBA's Issuing Agency Code.

   ICCBBA's policies for issuing unique identifiers conform to ISO/IEC 15459-2:2006(E); ISO/IEC 1549-4:2008; ISO/IEC 1549-6:2007. ICCBBA's issuing agency code is LI.

3. State whether ICCBBA uses only characters and numbers from the invariant character set of ISO/IEC 646.

   ICCBBA uses only characters and numbers from the invariant character set of ISO/IEC 646.

4. State whether any fee waivers or reductions are available. If fee waivers or reductions are available, please describe.

   ICCBBA charges a one-time fee to register and obtain a facility identification number and an annual fee for use of its data structures within bar codes on labeled products and access to its databases. The fees are reduced in countries classified as low (67% reduction) or medium (33% reduction) Human Development Index as defined by the United Nations. This would not apply to facilities within the US.

   Fees for access to the database are waived for government regulators (e.g., FDA), governmental and other organizations with an interest in vigilance and surveillance (e.g., CDC and WHO), and professional societies involved in accreditation (e.g., AATB, AABB, and FACT).

5. With the addition of MPHO Supplemental Identification Number and MPHO Supplemental Lot Number, please describe any changes to the UDI.

a. Could a UDI have both a DIN and MPHO Supplemental Lot Number? Previously, for HCT/Ps, the Lot/Batch Number flag was to be checked in GUDID if the UDI contained a DIN, but with the addition of the MPHO Supplemental Lot Number an additional checkbox may be needed in GUDID.

   A UDI could have both a DIN and a Lot Number. The DIN is essential to trace back to a donor. Some, but not all, tissue banks have an additional lot number. For some, this lot number identifies a sterilization batch. Because an HCT/P could be recalled based on a donor-related problem (utilizing the DIN) or a sterilization batch (based on the lot number), there is a need for both identifiers.

   We agree that there needs to be an additional checkbox in the GUDID to accommodate the DIN. Our thoughts on this were submitted in our comments to the GUDID guidance document. We believe that the DIN is a separate PI and should be treated as such.

b. Please explain the statement "If an additional identification number (e.g., supplemental serial number) exists, it may be encoded as part of the ISBT 128 data (not a PI) using Data Structure 036, MPHO Supplemental Identification Number." Would the MPHO Supplemental Identification Number never be a PI in the UDI, but could be included in the UDI?

   The Divisions Data Structure is the serial number for ISBT 128. This number is essential for traceability. It uniquely identifies a product when both the DIN and the Product Description Code (the Product Description Code is contained within the DI) are the same (e.g., two containers of Demineralized Bone Matrix from the same donor).

   Within some tissue bank computer systems there is a need for a serial number in addition to DIN, Product Description Code, and Product Divisions Code. This is an internal control mechanism where each and every product is given a distinct identifier.

   There cannot be two serial numbers in the UDI, and this additional serial number is not essential for traceability if the DI is present along with a DIN and Divisions Code (serial number) within the PI. Therefore, while we want to accommodate it within ISBT 128, it cannot be part of the PI.

   We have reworded our guidance document (attached) to clarify this.

c. What will be the maximum length of an ICCBBA issued UDI? 79 human readable characters or 67 database characters, per the table below.

Issuing Agency	Identifying Symbol	Identifier	Data Type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Donation Identification Number	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	Numeric [YYYJJJ)	8	6
ICCBBA	=}	Manufacturing Date	Numeric (YYYJJJ)	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		***Base UDI for HCT/Ps***	***Alphanumeric***	***79***	***67***
Ex of Human Readable Barcode: =/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20857

MEMORANDUM

Date: 1/30/2014

From: Caitilin Hamill, Ph.D.
Office of the Director
Center for Biologics Evaluation and Research

Subject: Application for ICCBBA as an FDA-accredited issuing agency

To: Nancy Stade, J.D.
Deputy Center Director for Policy
Office of the Center Director
Center for Devices and Radiological Health

Through: Christopher Joneckis, Ph.D.
Acting Associate Director for Review Management
Office of the Director
Center for Biologics Evaluation and Research

Through: Diane Maloney, J.D.
Associate Director for Policy
Office of the Director
Center for Biologics Evaluation and Research

CBER recommends accreditation of ICCBBA as an issuing agency for the purpose of issuing Unique Device Identifiers because it meets the eligibility and accreditation criteria under 21 CFR 830.100. ICCBBA has submitted an application for accreditation as an issuing agency for Unique Device Identifiers as well as supplemental information to support its application. The application and supplemental information contain the information required under 21 CFR 830.110(a).

The application documents ICCBBA'S conformance with international standards incorporated by reference into FDA regulations for issuing agencies. The application also provides ICCBBA's unique device identifier structure and the

data elements it will use. ICCBBA charges a one-time registration fee and an annual license fee based on the number of medical devices produced the previous year. Lastly, ICCBBA's protections against conflict of interest appear adequate.

The initial term of accreditation for ICCBBA will be 3 years. FDA may suspend or revoke the accreditation of ICCBBA in accordance with 21 CFR 830.130 if the issuing agency fails to fulfill the responsibilities of an FDA-accredited issuing agency, outlined in 21 CFR 830.120, or meets any other criteria under 21 CFR 830.130. Additionally, 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 unique device identifier, and ICCBBA may not implement that change until approved by FDA.

Concurrence:

Office	Name/Signature	Date
CBER/OD	Caitilin A. Hamill, Ph.D. **APPROVED** ***By Caitilin A. Hamill at 3:14 pm, Feb 07, 2014***	
CBER/OD	Christopher Joneckis, Ph.D.	
CBER/OD	Diane Maloney, J.D. **APPROVED**	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MEMORANDUM

Date: February 12, 2014

From: Erin Fields
Office or Surveillance and Biometrics
Center for Devices and Radiological Health

Subject: Application for ICCBBA as an FDA-accredited issuing agency

To: Nancy Stade, JD
Deputy Center Director for Policy
Office of the Center Director
Center for Devices and Radiological Health

Through: Terrie Reed
Associate Director
Informatics
Office or Surveillance and Biometrics
Center for Devices and Radiological Health

Through: Thomas Gross, MD
Director
Office or Surveillance and Biometrics
Center for Devices and Radiological Health

OSB recommends accreditation of ICCBBA as an issuing agency for the purpose of issuing Unique Device Identifiers because it meets the eligibility and accreditation criteria under 21 CFR 830.100. ICCBBA has submitted an application for accreditation as an issuing agency for Unique Device Identifiers as well as supplemental information to support its application. The application and supplemental information contain the information required under 21 CFR 830.110(a).

The application documents ICCBBA'S conformance with international standards incorporated by reference into FDA regulations for issuing agencies. The

application also provides ICCBBA's unique device identifier structure and the data elements it will use. ICCBBA charges a one-time registration fee and an annual license fee based on the number of HCT/P medical devices produced the previous year. Lastly, ICCBBA's protections against conflict of interest appear adequate.

The initial term of accreditation for ICCBBA will be 3 years. FDA may suspend or revoke the accreditation of ICCBBA in accordance with 21 CFR 830.130 if the issuing agency fails to fulfill the responsibilities of an FDA-accredited issuing agency, outlined in 21 CFR 830.120, or meets any other criteria under 21 CFR 830.130. Additionally, 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 unique device identifier, and ICCBBA may not implement that change until approved by FDA.

Draft: EFields 01/30/14
Reviewed: AHawthorn 2/4/14
Approved: TReed 2/10/14
Approved: