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

TABLE OF CONTENTS

(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.

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

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Patricia Distler
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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

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Patricia Distler

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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

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Patricia Distler

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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.

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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

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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**

Comments	**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**

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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ref:_00Dd0fegA._500j0wCkL:ref

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**

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					