

## HIBC Expiration Date Formats Comply with FDA UDI Requirements

FDA's published "Frequently Asked Questions, #A-4" (see below) states that "*the date format must be YYYYMMDD.*" However, it also states that "*this only applies to plain text dates on the device label*" and that "*Dates in the AIDC portion of the UDI.....are not subject to these date format requirements.*"

This exemption applies even in the event that you print a human readable version of the data in your bar code (typically directly beneath the symbol), because the human readable interpretation is part of the AIDC technology portion of the UDI. Per the HIBC Standard, it should exactly represent the machine-readable data in your code.

All of the following date formats are acceptable within your bar code/human readable AIDC:

MMYY  
YYMMDD  
YYMMDDHH  
YYJJJ  
YYJJJHH

Elsewhere on your package you should comply with the FDA-required plain text format.

You can visit the HIBCC website at <http://www.hibcc.org/create-hibc-udi-structures/> and create a sample HIBC UDI using any of the above date formats.

For additional questions contact HIBCC at (602) 381-1091 or by email at [info@hibcc.org](mailto:info@hibcc.org)

### **A.4. Question: Is there a standard format for dates on the device label?**

Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: the year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02. See [21 CFR 801.18\(b\)](#) for exceptions to this requirement. This requirement only applies to plain text dates on the device label. Dates in the AIDC technology portion of the UDI, or in the device history record, for example, are not subject to these date format requirements. In the event that a medical device expires in a particular month, but not a particular date, the labeler may choose the last day of the month for the date field because the date field is a requirement of the new format.

The standard date format is required for all medical devices unless excepted. This change should be implemented on the device label by the UDI compliance date for that device. Devices excepted from or not subject to the UDI regulation, must implement the standard date format by September 2018.