General exceptions from the requirement for the label of a device to bear a unique device identifier (§ 801.30)

Under § 801.30, the UDI rule provides general exceptions from UDI labeling requirements to certain categories of devices. A device within one or more of these exceptions is not required to bear a UDI. A labeler of a device identified in § 801.30 is not required to request an exception from FDA.

Request for an exception from or alternative to a UDI requirement (§ 801.55)

A labeler may submit a request for an exception from or alternative to the requirement for the label of a device to bear a unique device identifier (§ 801.20) or other UDI requirement under 21 CFR 801 Subpart B (Labeling Requirements for Unique Device Identification) for a specified device or a specified type of device.

In response to labeler requests or on our own initiative, the FDA may grant an exception or alternative if an exception is appropriate because the requirements of 21 CFR 801 Subpart B are not technologically feasible, or that an alternative would provide for more accurate, precise, or rapid device identification than the requirements of 21 CFR 801 Subpart B or would better ensure the safety or effectiveness of the device that would be subject to the alternative. If the FDA grants an exception or alternative, we may include any safeguards or conditions deemed appropriate to ensure the adequate identification of the device through its distribution and use. The FDA is making its decisions on labeler requests for exceptions and alternatives available at "FDA Decisions."

Considerations for Labelers

In order to establish a system to adequately identify medical devices through distribution and use, the FDA expects that the labels of almost all devices are capable of bearing, and should in fact bear a unique device identifier (UDI) on the label, unless excepted under § 801.30.

Under 21 CFR 801.55(c), FDA will consider granting requests for an exception from a UDI requirement if the requirement is not technologically feasible. We expect that such situations will be rare. FDA does not consider exception requests that are based on reasons other than technological infeasibility (including, but not limited to, financial burden, a claimed low rate of adverse events, or a claim that the product is somehow unique such that adverse events do not occur).

Labelers may consider the following to address issues of inadequate label size or unique packaging that may create challenges to having the device label bear its UDI in both easily readable plain-text and AIDC forms:

1. Remove or minimize information on the label that is not required under 21 CFR 801 (or 21 CFR 809.10, if your device is an in vitro diagnostic product). See 21 CFR 801.15 for more information on prominence of required label statements.

2. Increase the size of the label or modify the label e.g., move label to a flatter location on the immediate container) to accommodate the UDI.

3. Use a smaller form of AIDC technology or split the AIDC form into multiple segments. The easily readable plain-text UDI may also be split into multiple segments.

If the approaches described above cannot be used to address a labeler's concerns, the labeler may consider submitting a request for an alternative under 21 CFR 801.55 to add an overwrap that would bear the UDI or place another label bearing the UDI elsewhere on the packaging.

To request an exception from or alternative to the requirements of 21 CFR 801 Subpart B:

- Submit a UDI exception/alternative inquiry below. In response, the FDA UDI Help Desk will email instructions for requesting an exception from or alternative to a UDI requirement. If you do not receive an immediate reply in your inbox, please check the spam/junk folder. If the email was sent to your spam/junk folder, please adjust your filter to recognize the UDI Help Desk as a contact.

- Review the instructions and include the necessary information in your request.

- Submit the request as indicated in the instructions. An FDA UDI Help Desk Analyst will respond to your request.

Help Desk Exceptions/Alternatives Inquiry Form

Go to: **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery**

Complete form and submit.

According to 21 CFR 801.55 (a), when submitting your request for an exception or alternative you must:

- Identify the device or devices that would be subject to the exception or alternative;

- Identify the provisions of 21 CFR 801 Subpart B that are the subject of the request for an exception or alternative;

- If requesting an exception, explain why the requirements of 21 CFR 801 Subpart B are not technologically feasible;

- If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of 21 CFR 801 Subpart B or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative;

- If known, provide the number of labelers and the number of devices that would be affected if we grant the requested exception or alternative; and

- Provide other requested information needed to clarify the scope and effects of the requested exception or alternative.