From: OC GCP Questions
To: [redacted]
Subject: IUO Labeling of material - IVD
Date: Wednesday, March 27, 2019 8:26:24 AM
Attachments: [redacted]

For FDA-regulated investigational products CFR 312.6 would apply.

Labeling of an investigational product can be found und 21 CFR 312.6. See below.

Sec. 312.6 Labeling of an investigational new drug.

(a) The immediate package of an investigational new drug intended for human use shall bear a label with the statement "Caution: New Drug--Limited by Federal (or United States) law to investigational use."

(b) The label or labeling of an investigational new drug shall not bear any statement that is false or misleading in any particular and shall not represent that the investigational new drug is safe or effective for the purposes for which it is being investigated.

(c) The appropriate FDA Center Director, according to the procedures set forth in 201.26 o

610.68 of this chapter, may grant an exception or alternative to the provision in paragraph (a) of this section, to the extent that this provision is not explicitly required by statute, for specified lots, batches, or other units of a human drug product that is or will be included in the Strategic National Stockpile.

Additionally, there would need to be the standard type of information that would be included on a prescription bottle. There would need to be information about the patient, the directions for use, the product contained in the bottle, the date it was filled, expiration date, and the prescriber's information. This would likely be determined under state law. If you are transferring the product to a different container, you would probably need to keep information about which product you used and what lot numbers are involved.

For devices (IVDs are considered devices) CFR 812.5 would apply.

812.5 Labeling of investigational devices.

(a) Contents. An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with §801.1), the quantity of contents, if appropriate, and the following statement: “CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.” The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

(b) Prohibitions. The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated.

(c) Animal research. An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement: “CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects.”

(d) The appropriate FDA Center Director, according to the procedures set forth in §801.128 or §809.11 of this chapter, may grant an exception or alternative to the provisions in paragraphs (a) and (c) of this section, to the extent that these provisions are not explicitly required by statute, for specified lots, batches, or other units of a device that are or will be included in the Strategic National Stockpile.

It would be a matter of what would be required by the state as well.

Additionally you might want to contact the Center for Devices (CDRH) at DICE@fda.hhs.gov or the Center for Drugs (CDER) at druginfo@fda.hhs.gov

Please see FDA's IVD website. There is a phone number at the bottom of the page.
In Vitro Diagnostics

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, March 25, 2019 1:31 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IUO Labeling of material - IVD

Many of the products we would like to perform clinical trials on in the US are already CE marked. We often receive the products from our European facility already labeled with an IUO label, but there is also the IVD mark on the outside box and on the inside (such as bottles). My question is does the IVD need to be marked out on everything when the material will be sent to a clinical trial site for IUO studies?

Many thanks,

[redacted]