From: OC GCP Questions
To: [redacted]
Subject: IMP labeling requirements in USA
Date: Thursday, June 11, 2015 12:08:36 PM

Good morning –

I forwarded your email to the Center for Drugs (CDER). They responded with the following information (below).

In addition to 21 CFR312.6, we can provide you will very basic information but strongly suggest you contact the appropriate review division as the division may have other suggestions on what needs to be included on the investigational product label. As a rule of thumb, the label of an IND drug product should comply with the general labeling requirements under 21 CFR 201.1. It may also need to comply with other requirements such as 21 CFR 201.17 (lot no.) and 201.18 (exp. date).

A review of CDER's 03/01/91 GUIDELINE ON THE PREPARATION OF INVESTIGATIONAL NEW DRUG PRODUCTS
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070315.pdf provides an "exemption" from 21 CFR 201.18: "For investigational new drug products, certain labeling information may be provided separately from the drug container, where it is essential to the clinical study objectives that the drug(s) be provided as "blinded." In such cases a code-breaking guide is furnished to each investigator for emergency uses. FDA would not object if, for "blinding" purposes, the lot or control number is not visible on such containers but is provided separately forcode-breaking purposes."
21 CFR: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200421

Again, we think contacting the appropriate review division would be your best source of labeling information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, June 11, 2015 12:41 AM
To: OC GCP Questions
Subject: Re: IMP labeling requirements in USA

Dear Doreen,

Good morning and many thanks for the prompt reply.

We have been following IMP labeling requirements in USA as per Sec. 312.6 Labeling of an investigational new drug.

In below email you have mentioned about additional information, could you let us know whether this is mandatory to be included on the IND labels and what exact information to be included on IND labels?

Your early response will be highly appreciated.

Thank you in-advance.

Best regards,

[redacted]

On Wed, 10 Jun 2015 18:37:14 +0530 OC GCP Questions wrote
>

Good morning –

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.

CFR - Code of Federal Regulations Title 21

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 or 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.

As mentioned, it would be a matter of what would be required by the state as well.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards

Doreen M. Kezer, MSN

Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From:

Sent: Wednesday, June 10, 2015 8:41 AM

To: OC GCP Questions

Subject: IMP labeling requirements in USA

Dear Sir/Madam,

As an introduction I am [redacted] and would request responses to below:

1. Could you let us know the IMP labeling requirements in USA?

We follow Code of Federal Regulations, as given in Section 312.6 Labeling of an investigational new drug, Title 21, Volume 5, Revised as of April 1, 2014, CITE: 21CFR312.6 for the labeling of IMP.

Your early response will be highly appreciated.

Many thanks in-advance.

Best regards,

[redacted]