

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question Regarding Mandated OTC Supportive Medication in trials
Date: Tuesday, August 12, 2014 9:38:13 AM

Good morning –

We consulted the Center for Drugs (CDER) for an answer to your question. Please see their response below.

Kind regards

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: CDER DRUG INFO
Sent: Tuesday, August 12, 2014 7:43 AM
To: OC GCP Questions
Subject: RE: Question Regarding Mandated OTC Supportive Medication in trials

Hi Doreen,

I think it would be up to the sponsor how they wish to source the product. It would also be discussed with the review team and if OND had any suggestions they would bring this up during the protocol review. I don't know of any overarching guidelines though regarding how exactly such an OTC should be sourced.

If the product is being used in a trial, however, I would imagine that the sponsor would want consistency to eliminate any chance of variability, contamination, etc...

Hope this helps

Division of Drug Information/Small Business Assistance/ AskGDUFA

From: [redacted]
Sent: Monday, August 11, 2014 8:11 AM
To: OC GCP Questions
Subject: Question Regarding Mandated OTC Supportive Medication in trials

If a sponsor wishes to mandate, in the protocol, that subjects use a particular over the counter medication (eg anti-histamine or eye drops etc), what regulations govern the supply of and distribution of the OTC medication?

Is it simply sufficient to source & supply in a "kit" or do labeling, accountability & lot control obligations as per any IMP need to be addressed?

Is it appropriate to instruct PI's to supply the medication through their own institution?

Regards,

[redacted]